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Shturman

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[54] METHOD AND APPARATUS FOR IN VIVO HEART VALVE DECALCIFICATION

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Related U.S. Application Data

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[51] Int. Cl.⁶ A61M 31/00

[52] U.S. Cl. 604/49; 604/53; 128/898

[58] Field of Search 604/28, 49, 52, 53, 604/96; 606/191-194, 159; 128/898

[56] References Cited

U.S. PATENT DOCUMENTS

4,445,509	5/1984	Auth .	
4,589,412	5/1986	Kensley	606/192
4,625,712	12/1986	Wampler .	
4,784,636	11/1988	Rydell	606/194
4,790,310	12/1988	Ginsburg et al. .	
4,790,813	12/1988	Kensley	606/159
4,817,586	4/1989	Wampler	600/16
4,846,152	7/1989	Wampler et al.	600/16
4,894,051	1/1990	Shiber	606/159
4,944,722	7/1990	Carriker et al.	600/16
4,979,951	12/1990	Simpson	606/159
4,990,134	2/1991	Auth	604/22
5,009,659	4/1991	Hamlin et al.	606/194
5,092,873	3/1992	Simpson et al.	606/170
5,100,424	3/1992	Jang et al.	606/159
5,167,628	12/1992	Boyles	604/96
5,181,911	1/1993	Shturman	604/96
5,188,635	2/1993	Radtke	606/14
5,221,258	6/1993	Shturman	604/96

FOREIGN PATENT DOCUMENTS

0260711	9/1987	European Pat. Off.	A61M 25/00
8906935	1/1989	WIPO	A61B 17/22
8905611	6/1989	WIPO .	
9007909	7/1990	WIPO .	
9101690	7/1990	WIPO	A61B 17/36

OTHER PUBLICATIONS

Bom, et al, "Early and Recent Intraluminal Ultrasound Devices," *International Journal of Cardiac Imaging*, 4:79-88, 1989.

Rutan, et al, "Initial Experience with the Hemopump," *Critical Care Nursing Clinics of North America*, vol. 1, No. 3, Sep. 1989, pp. 527-534.

Frazier, et al, "First Human Use of the Hemopump, a Catheter-Mounted Ventricular Assist Device," *Ann. Thorac. Surg.*, 1990:49:299-304.

McCarty, "Catheter Clears Coronary Arteries," *Design News*, Sep. 1991, pp. 88-92.

Bashore, "Balloon Valvuloplasty," *Invasive Cardiology—Principles and Techniques*, pp. 145-147.

Block, "Percutaneous Mitral and Aortic Valvuloplasty," *The Practice of Cardiology*, 2d ed., Ch. 26, pp. 879-891 1989.

Campbell, et al, "Conservative Aortic Valve Intervention: Thwarted Again!," *JACC*, vol. 16, No. 3, Sep. 1990:631:2.

Shawl, et al, "Percutaneous Cardiopulmonary Bypass Support in the Catheterization Laboratory: Technique and Complications," *American Heart Journal*, vol. 120, No. 1, Jul. 1990, pp. 195-203.

(List continued on next page.)

Primary Examiner—C. Fred Rosenbaum

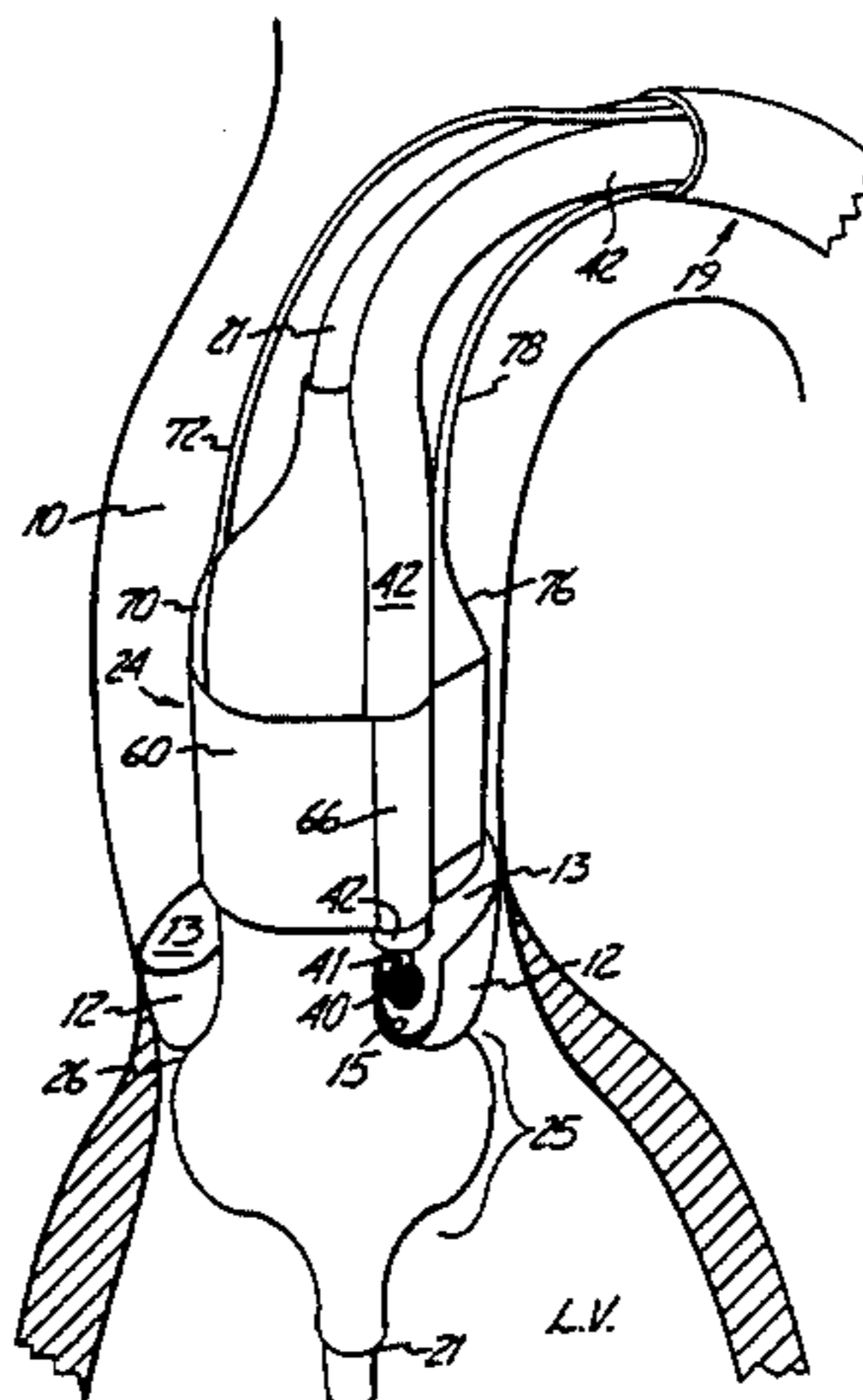
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Attorney, Agent, or Firm—Gregory P. Kaihoi

[57] ABSTRACT

A method and apparatus for in vivo removal of calcified deposits from an aortic valve. The apparatus includes an anchoring balloon catheter fixatable across the aortic valve, a tool for removing the deposits, and a mechanism means for securing the tool with respect to the anchoring balloon and the aortic valve. The method involves advancing an anchoring balloon catheter through the aorta and positioning it across the aortic valve, inflating the anchoring balloon to fixate it with respect to the aorta and aortic valve, and then operating a deposit removal tool secured to the anchoring balloon to remove the deposits.

14 Claims, 36 Drawing Sheets



OTHER PUBLICATIONS

- O'Keefe, et al, "Natural History of Candidates for Balloon Aortic Valvuloplasty", *Mayo Clin. Proc.*, Nov. 1987, 62:986-991.
- Booth, "Aortic Stenosis and the Potential of Balloon Aortic Valvuloplasty," *Masters in Cardiology*, vol. 5, Spring 1988:11-13.
- Levinson, et al, "Octogenarians With Aortic Stenosis," *Circulation*, vol. 80, No. 3, Sep. 1989 (Suppl. I):49-56.
- Fremes, et al, "Valvular Surgery in the Elderly," *Circulation*, vol. 80, No. 3, Sep. 1989 (Suppl. I):77-90.
- Craver, et al, "Predictors of Mortality, Complications, and Length of Stay in Aortic Valve Replacement for Aortic Stenosis," *Circulation*, vol. 78, No. 3, Sep. 1988 (Suppl. I):85-90.
- Enright, et al., "Aortic Debridement—Long-term Follow-up," *Circulation*, vols. 43 and 44, May, 1971 (Suppl. I):68-72.
- Safian, et al, "Postmortem and Intraoperative Balloon Valvuloplasty of Calcific Aortic Stenosis in Elderly Patients: Mechanism of Successful Dilatation," *JACC*, vol. 9, No. 3, Mar. 1987:655-60.
- Cribier, et al, "Feasibility and Safety of Balloon Aortic Valvuloplasty in Patients Under 70 Years of Age," *Circulation*, 1987:76 (Suppl. 4).
- Holmes, et al, "The Safety and Efficacy of a Dual-balloon Approach During Percutaneous Aortic Balloon Valvuloplasty," *Circulation*, vol. 76, Oct. 1987 (Suppl. 4).
- Kuntz, et al, "Follow-up of Balloon Aortic Valvuloplasty: Results in 192 Cases," *JACC*, vol. 13, No. 2, Feb. 1989, 16A.
- Feldman, et al, "Second Dilatation for Restenosis Following Successful Balloon Aortic Valvuloplasty: Results, Pathology and Mechanism," *JACC*, vol. 13, No. 2, Feb. 1989, 17A.
- Davidson, et al, "Failure of Balloon Aortic Valvuloplasty to Result in Sustained Clinical Improvements in Patients With Depressed Left Ventricular Function," *JACC*, vol. 13, No. 2, Feb. 1989, 17A.
- Spielberg, et al, "One-Two Year Follow-up After Primarily Successful Valvuloplasty for Calcified Aortic Stenosis," *JACC*, vol. 13, No. 2, Feb. 1989, 16A.
- "Aortic Valvuloplasty Gives Major Gain for Small, Select Pt Subpopulation," *The Newspaper of Cardiology*, Mar. 1990:17.

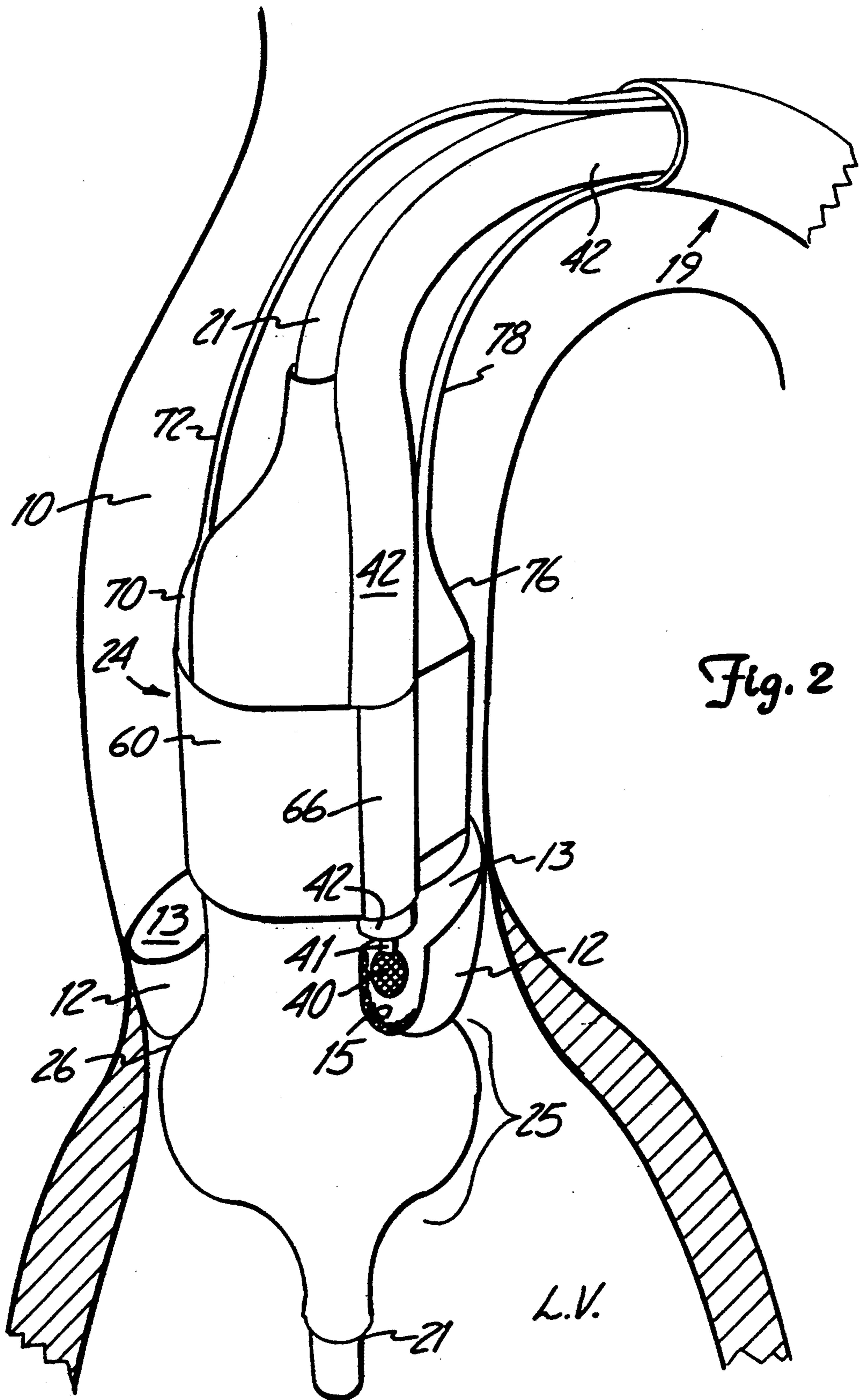


Fig. 2

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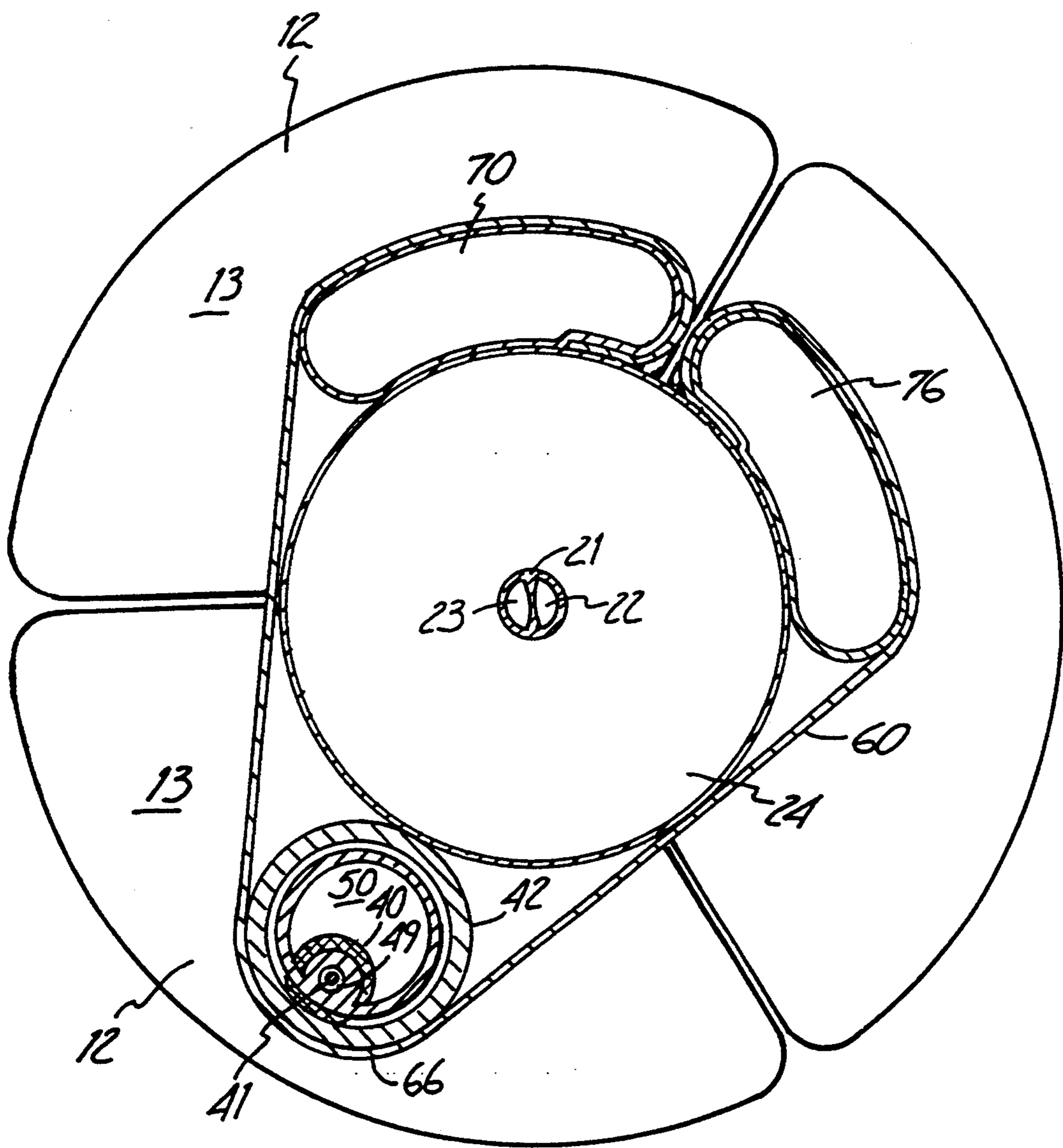


Fig. 3

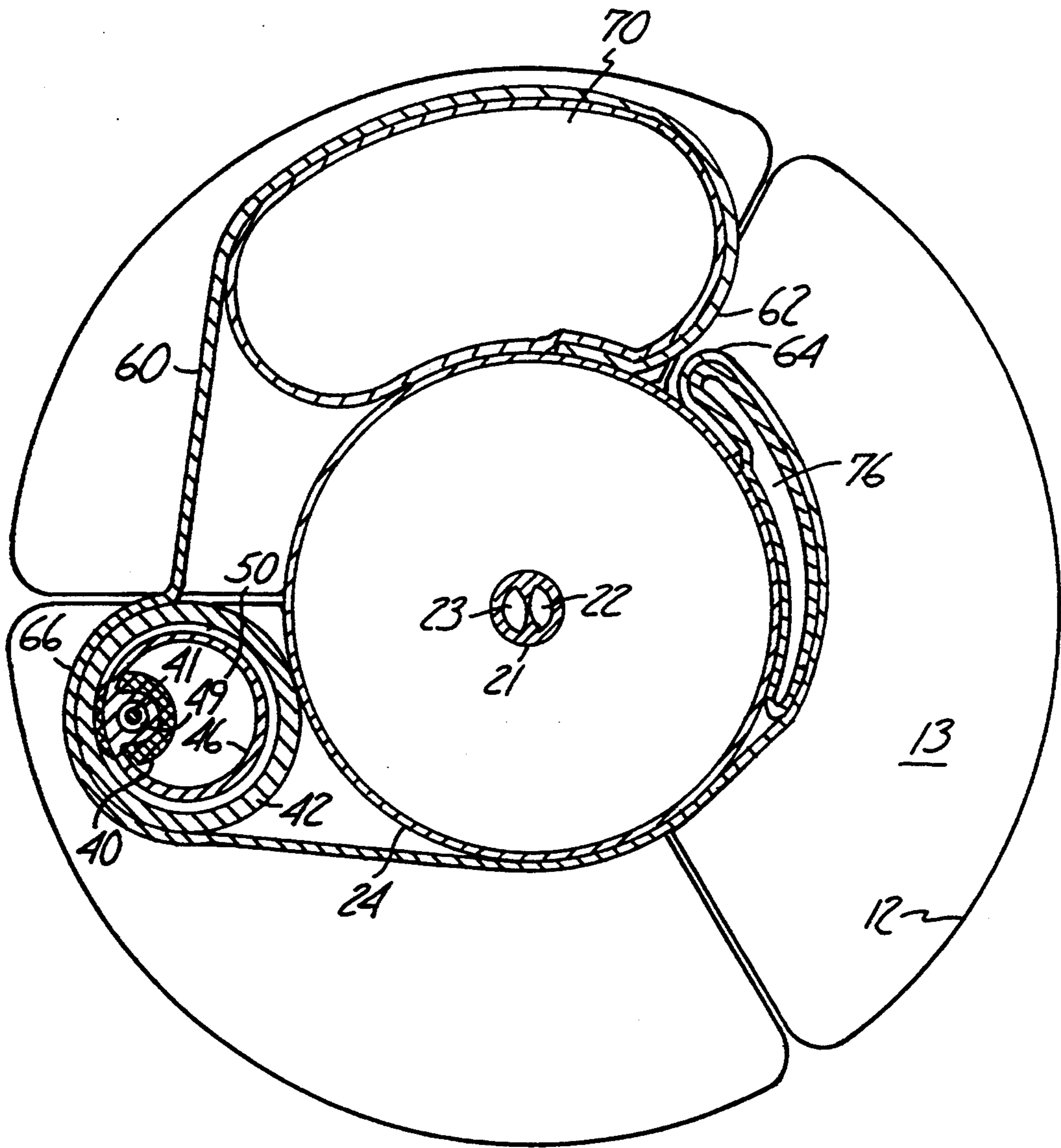


Fig. 4

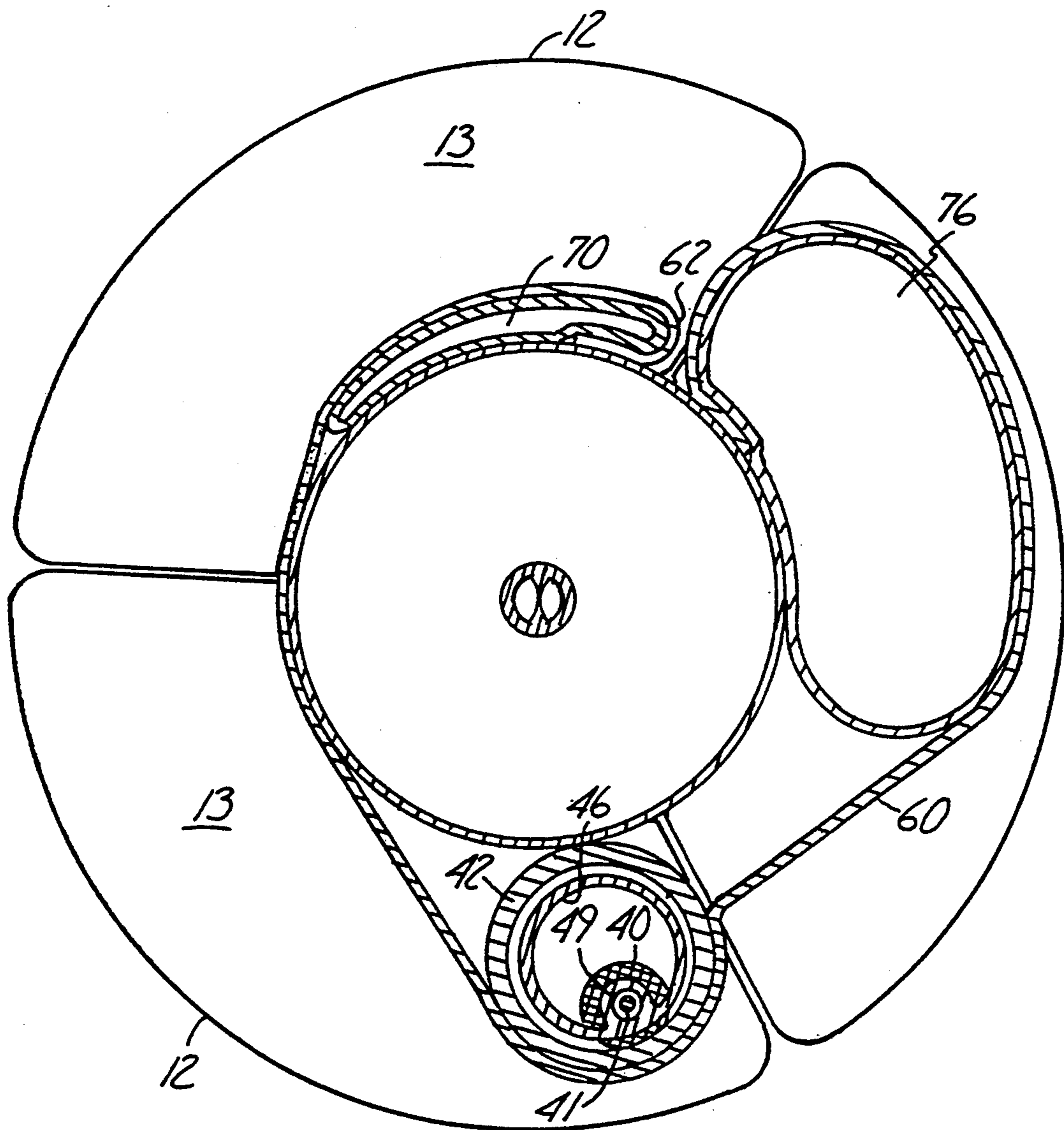


Fig. 5

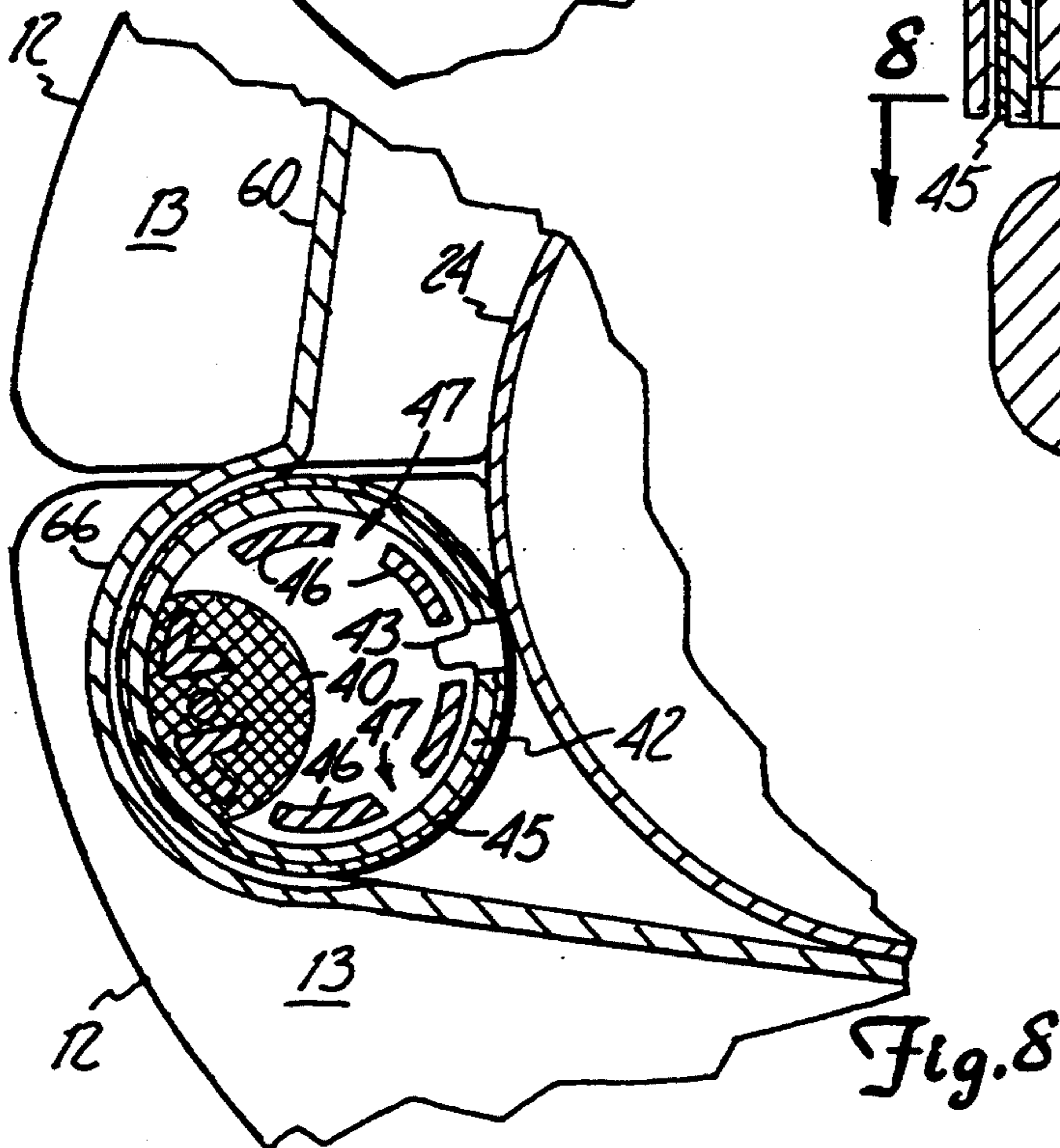
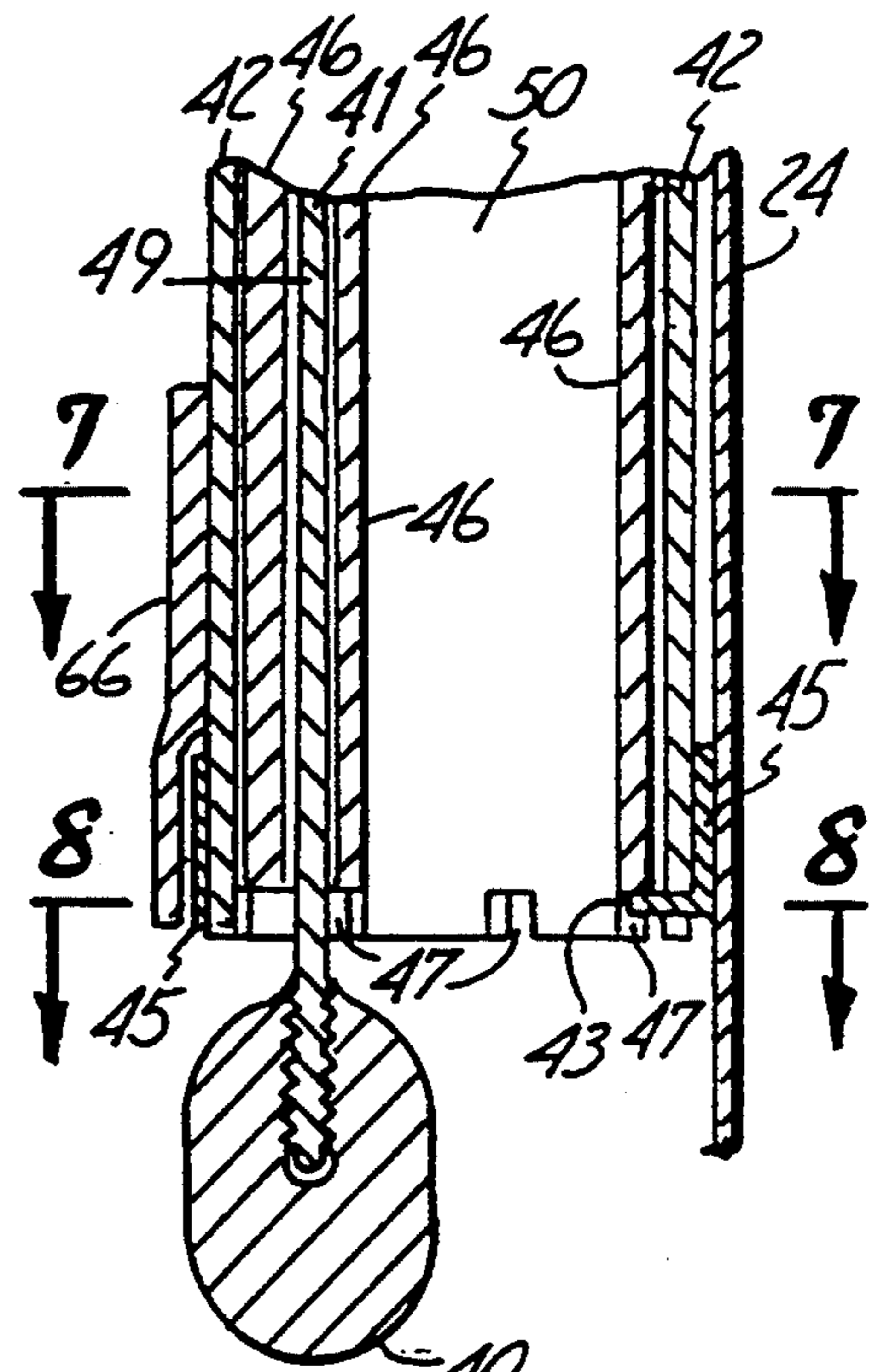
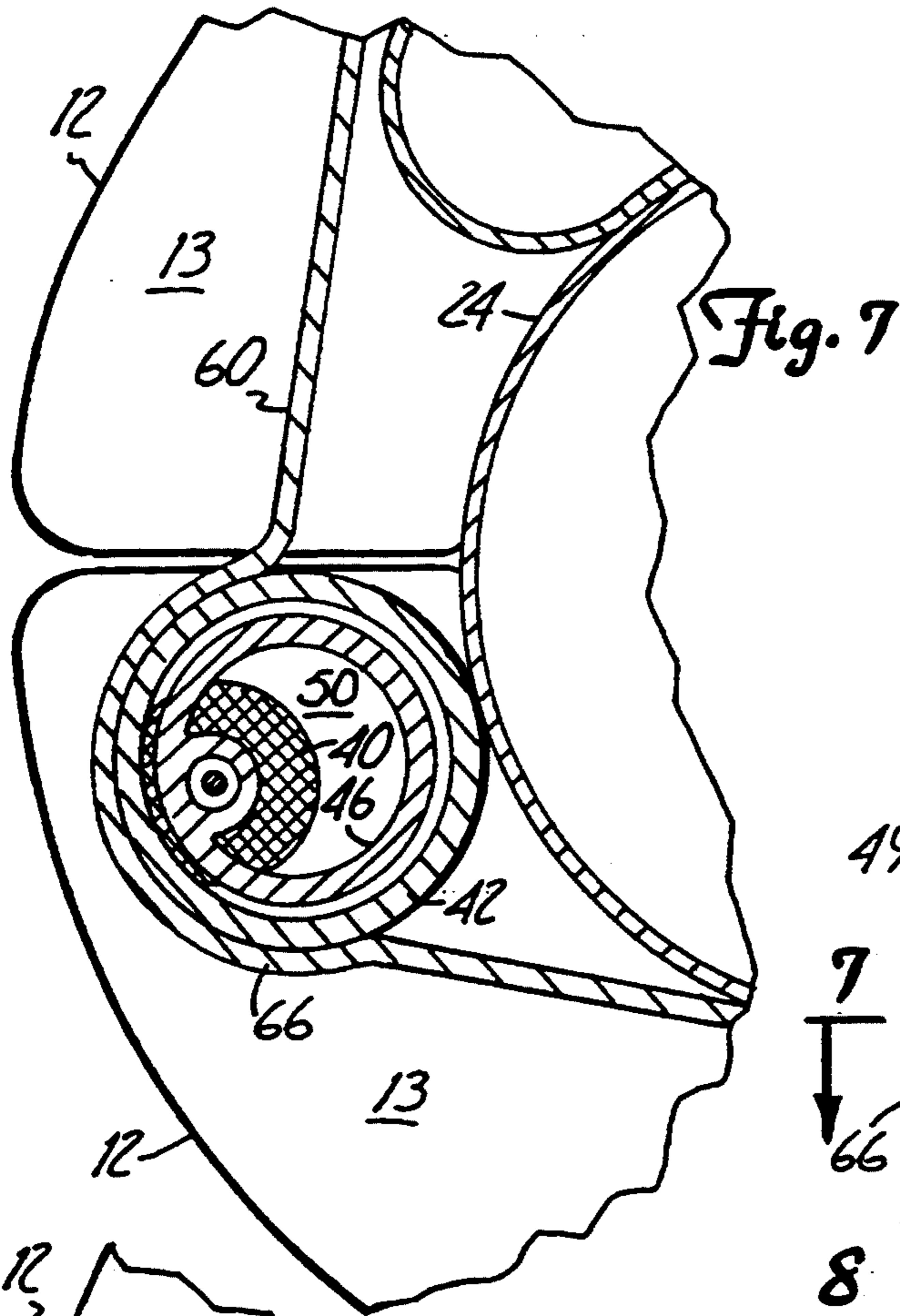
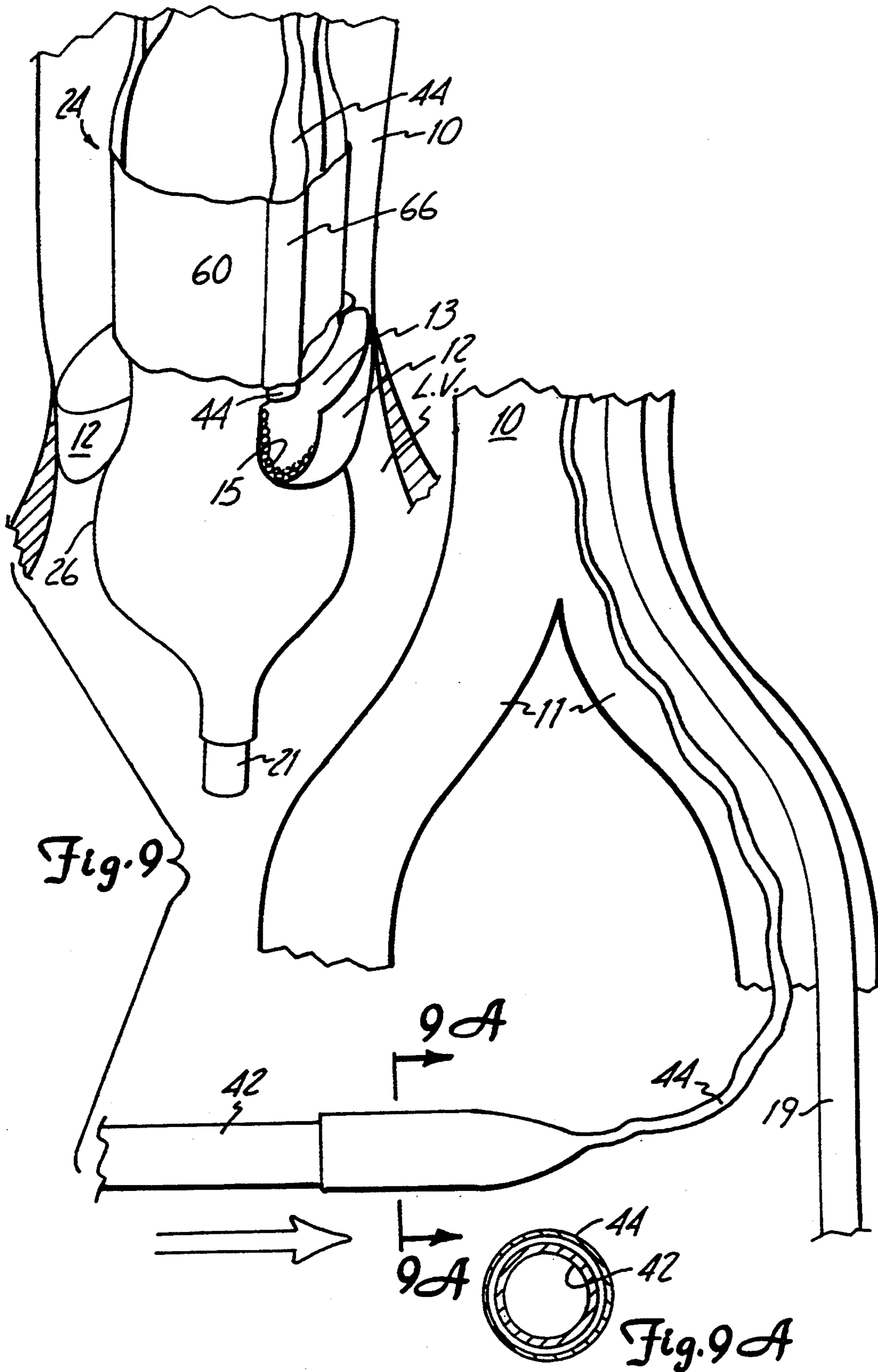
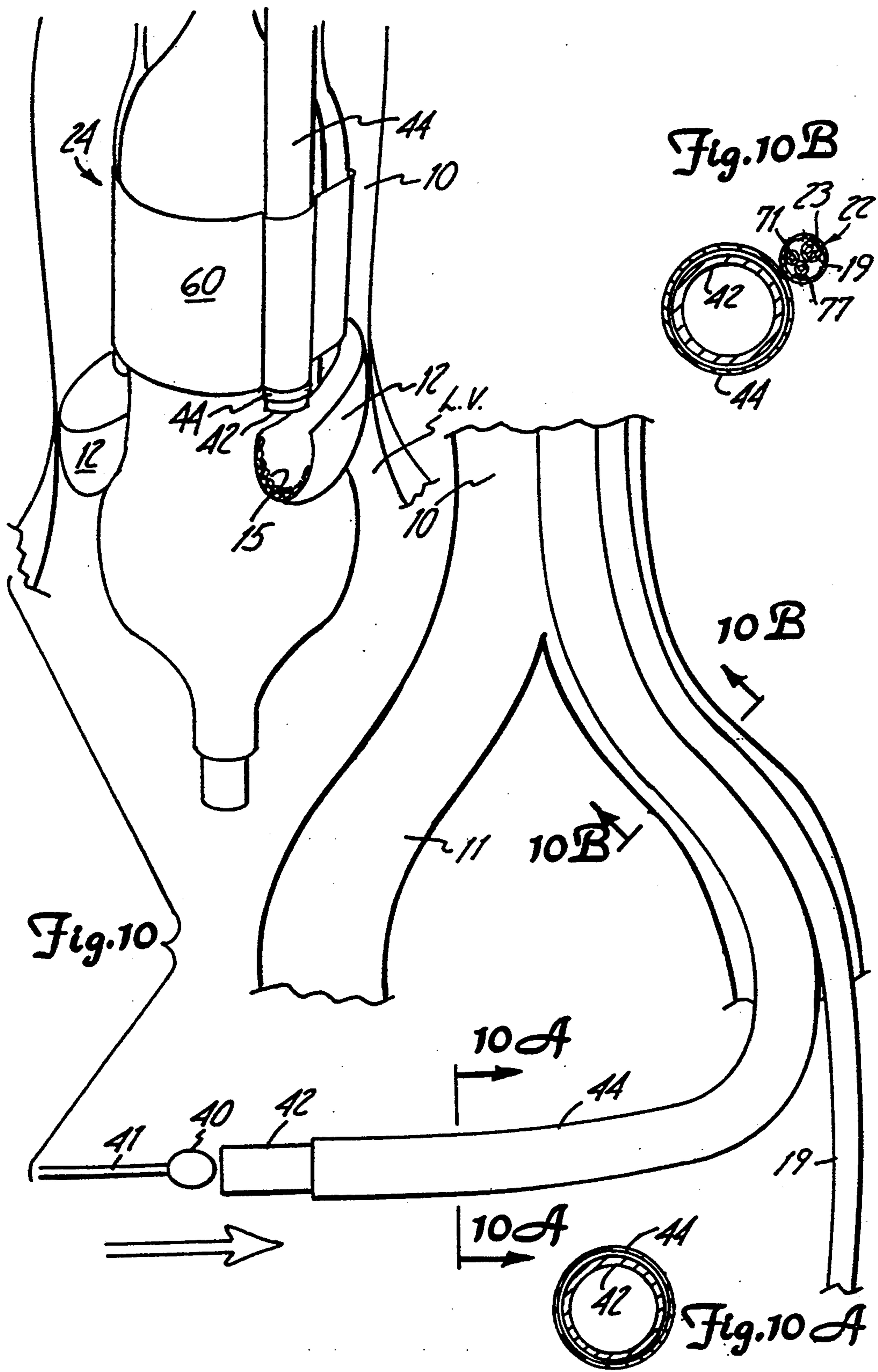
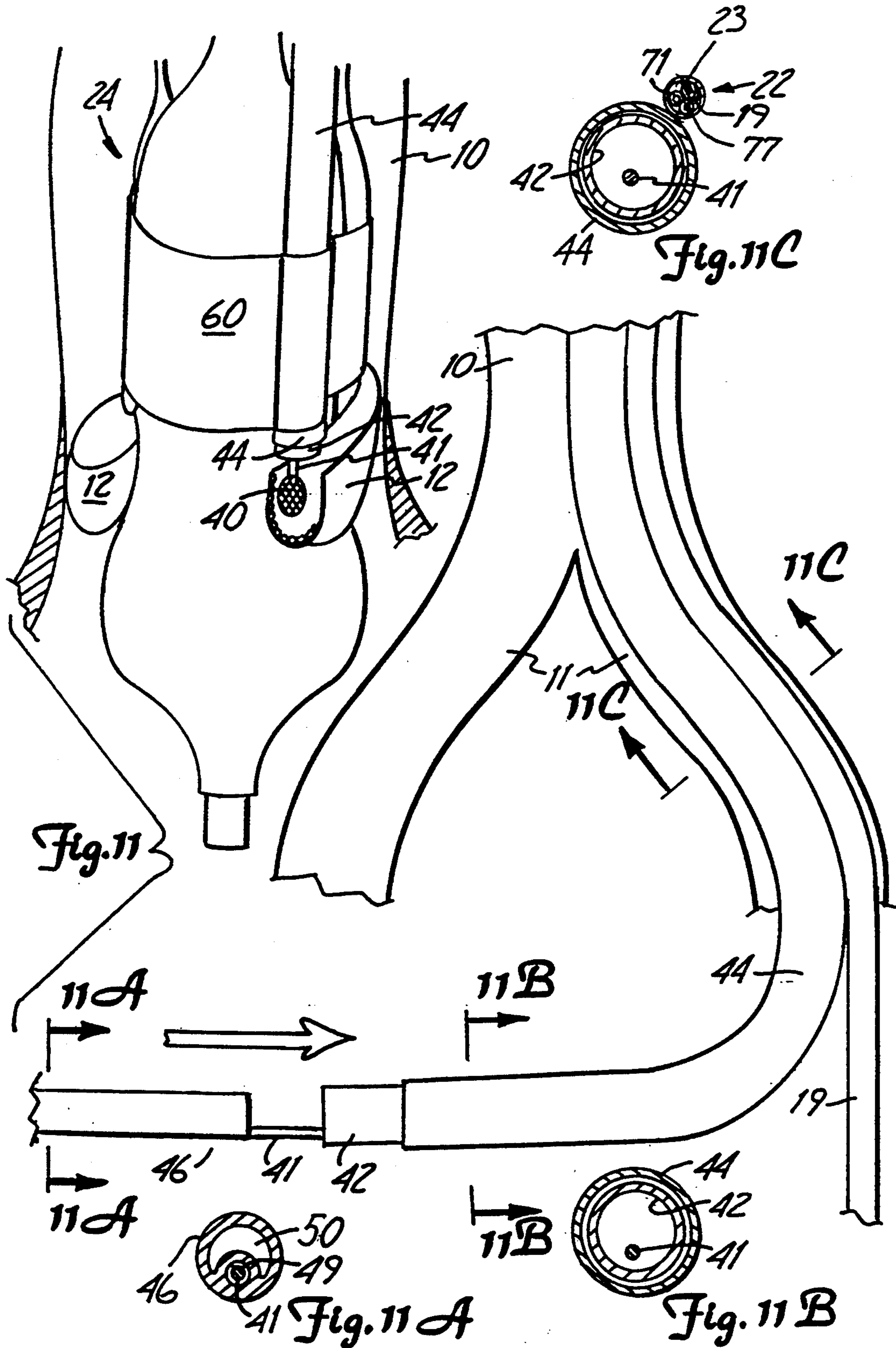


Fig. 6

Fig. 8







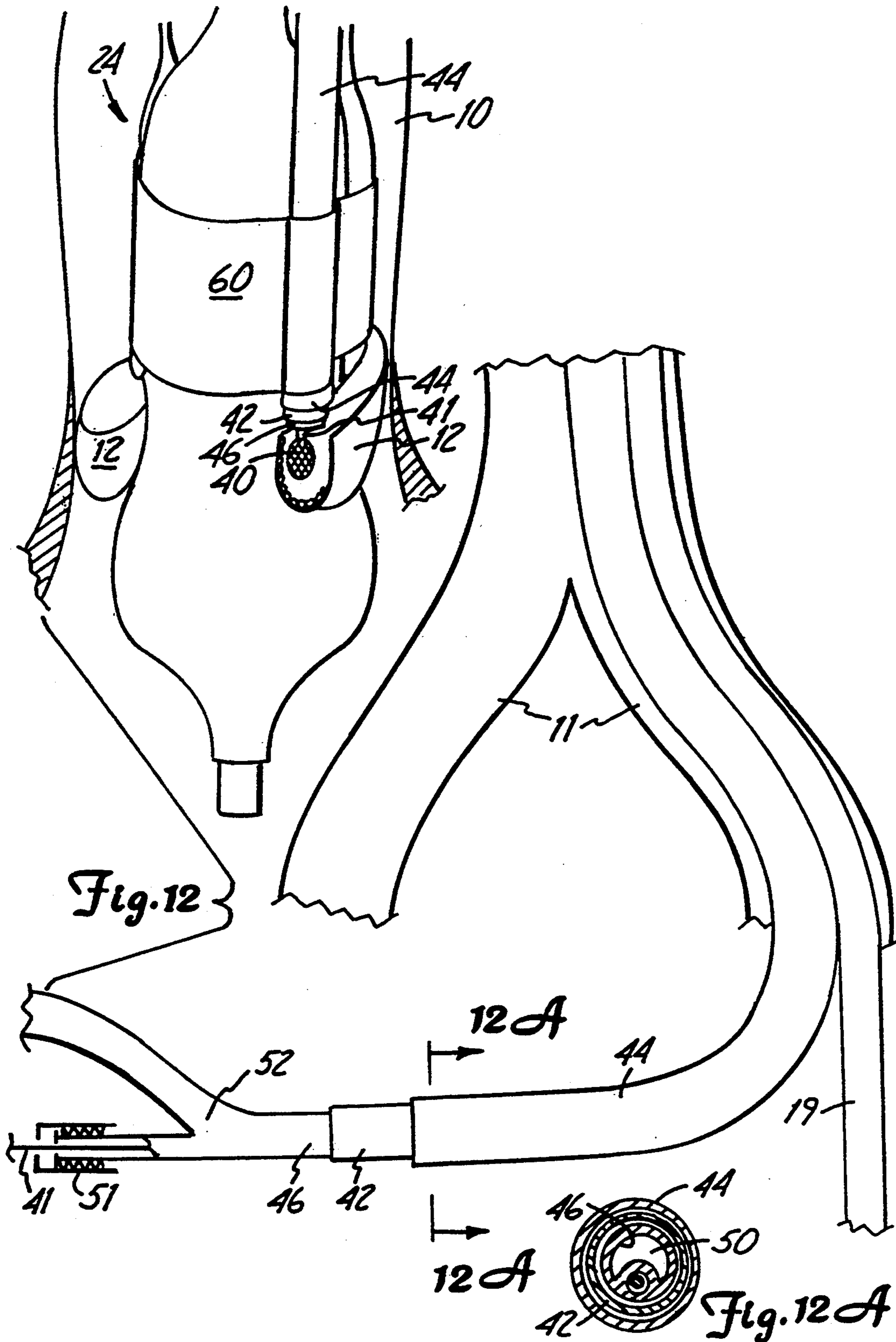
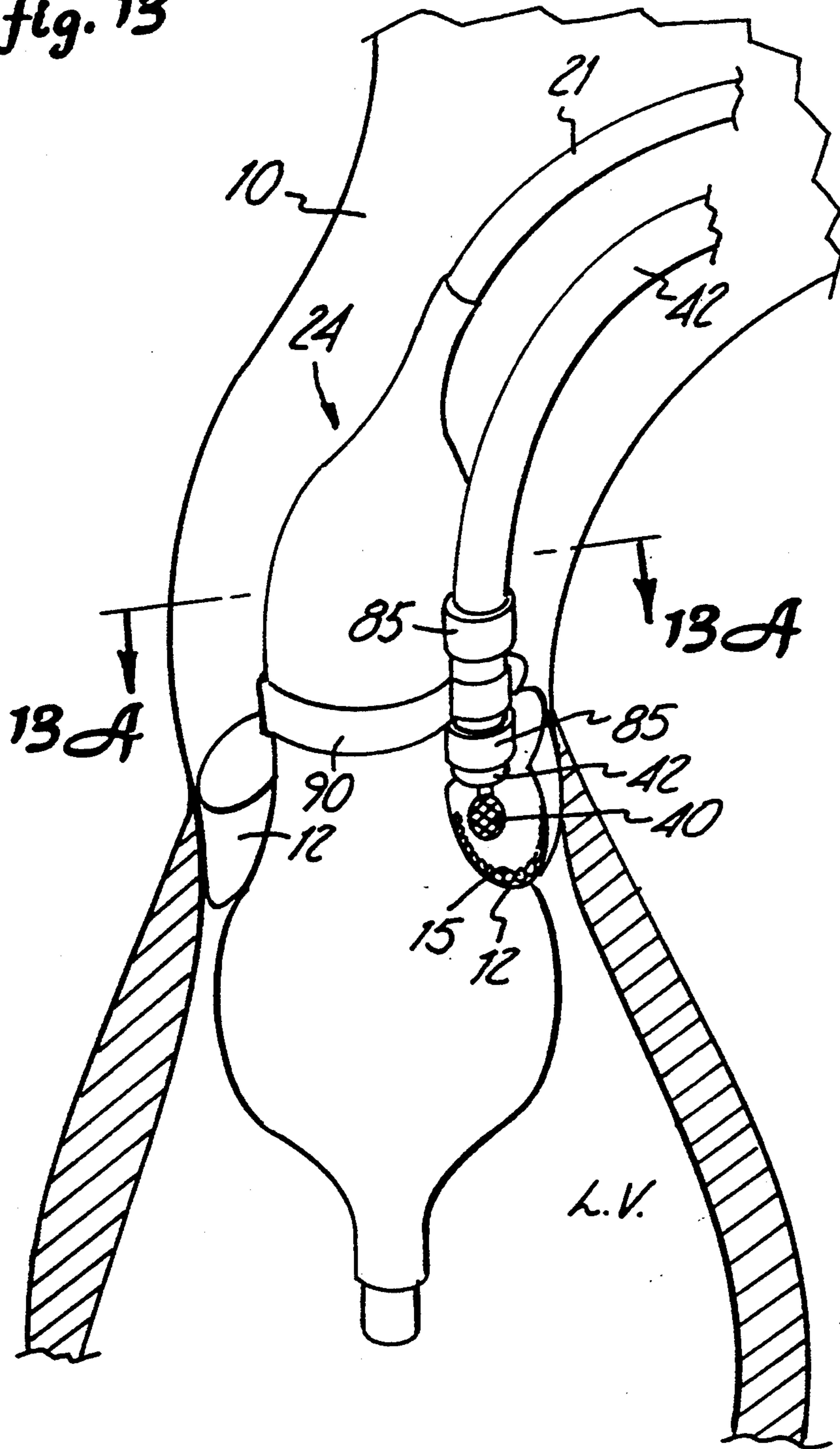


Fig. 13



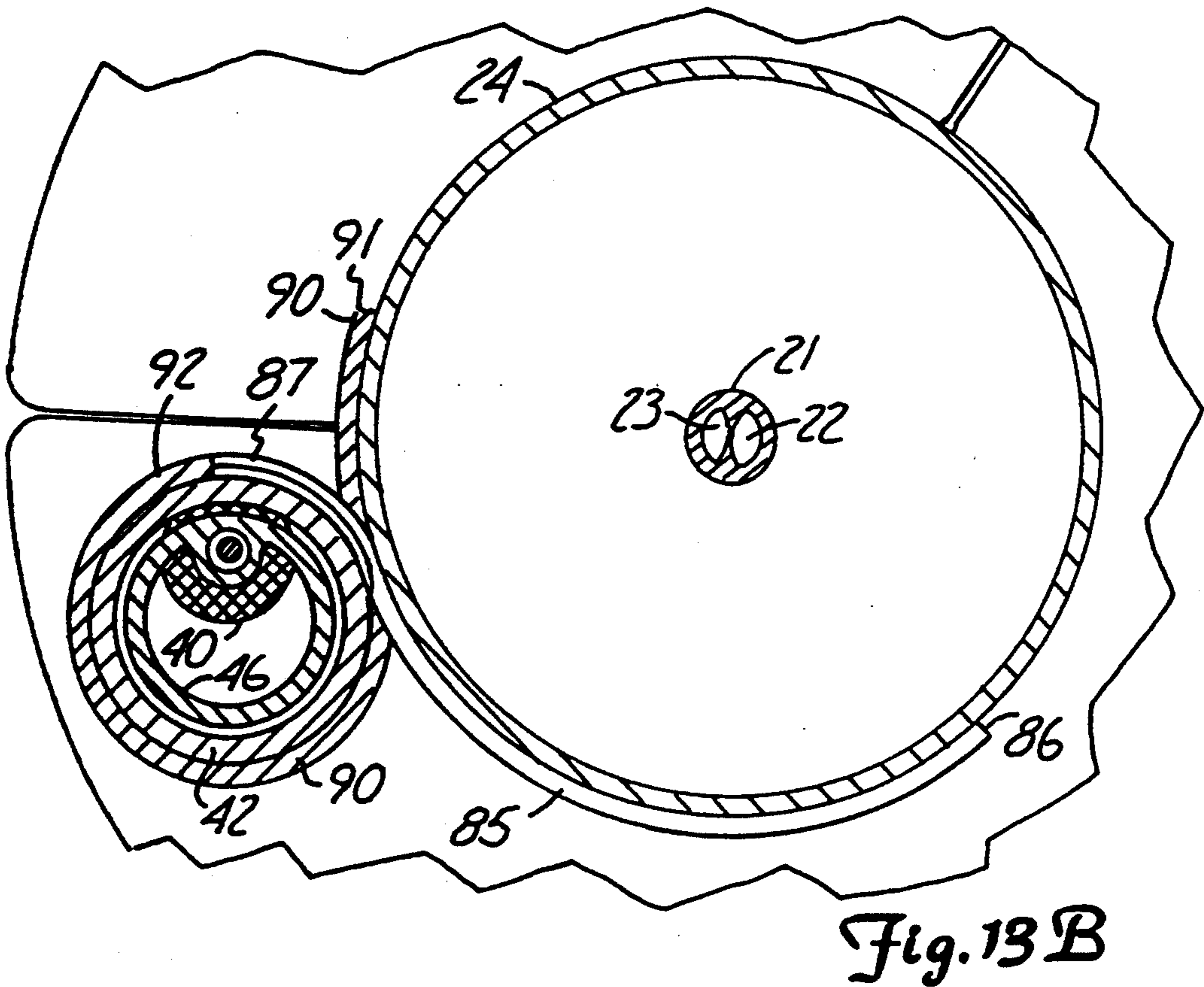
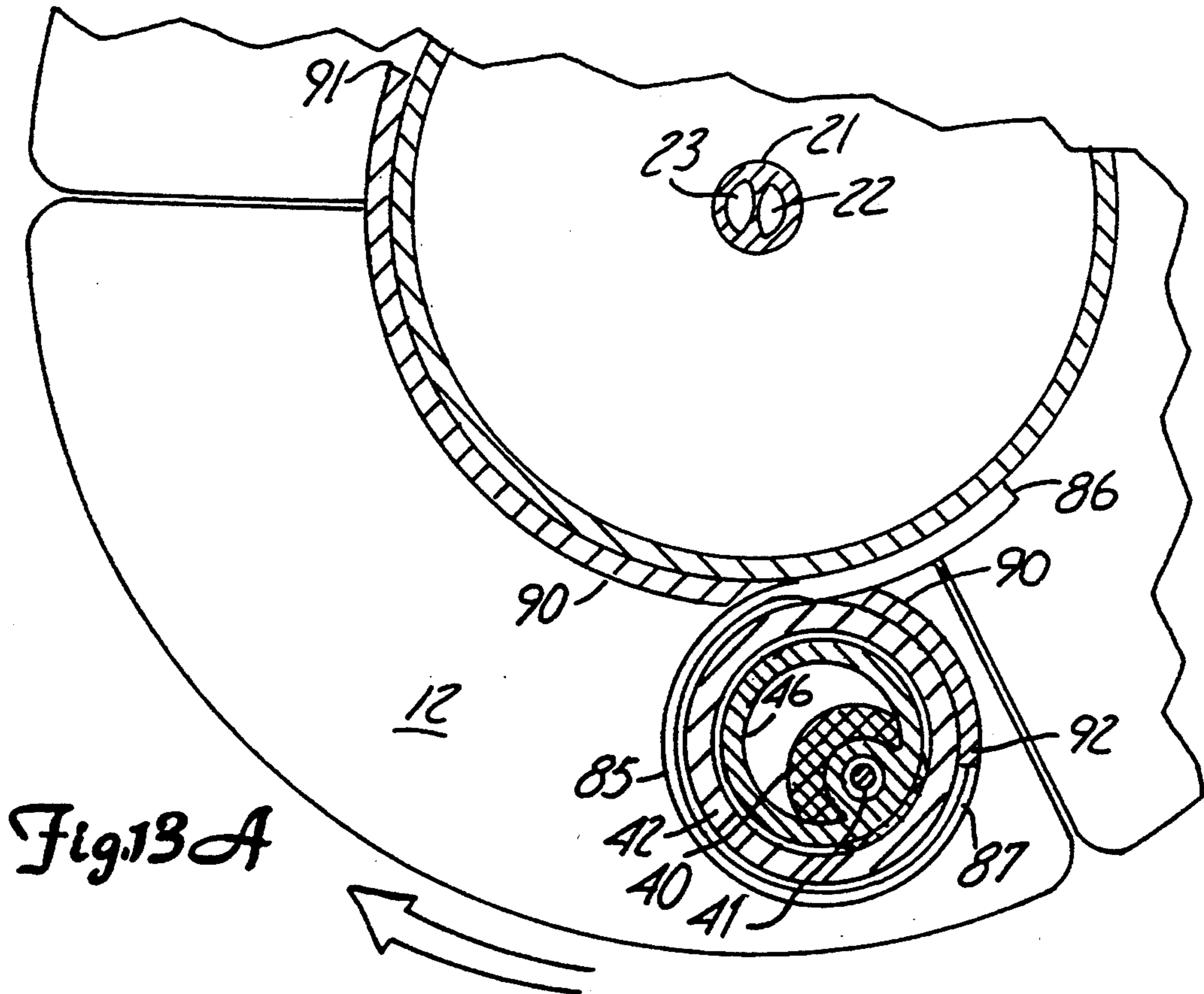
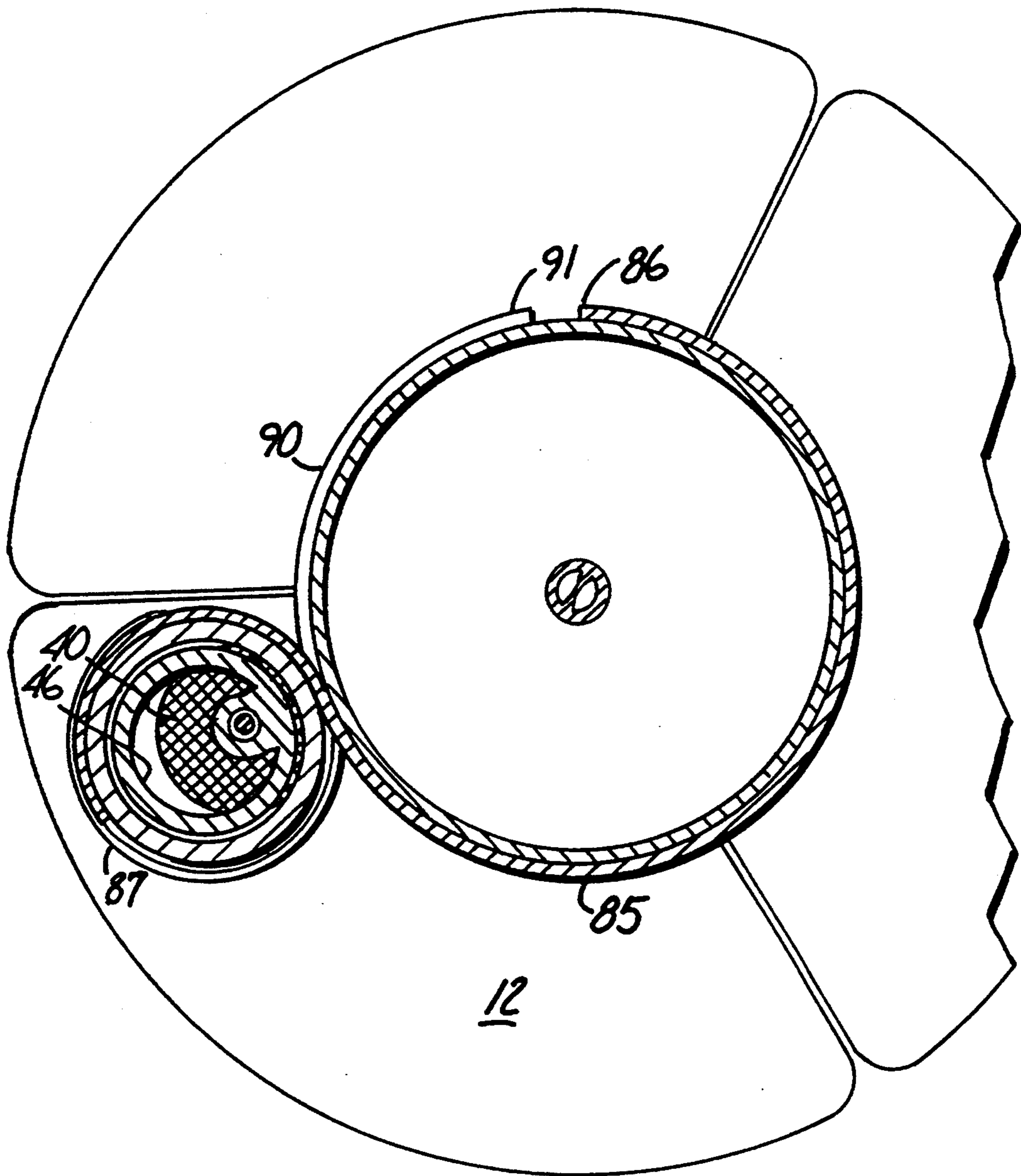
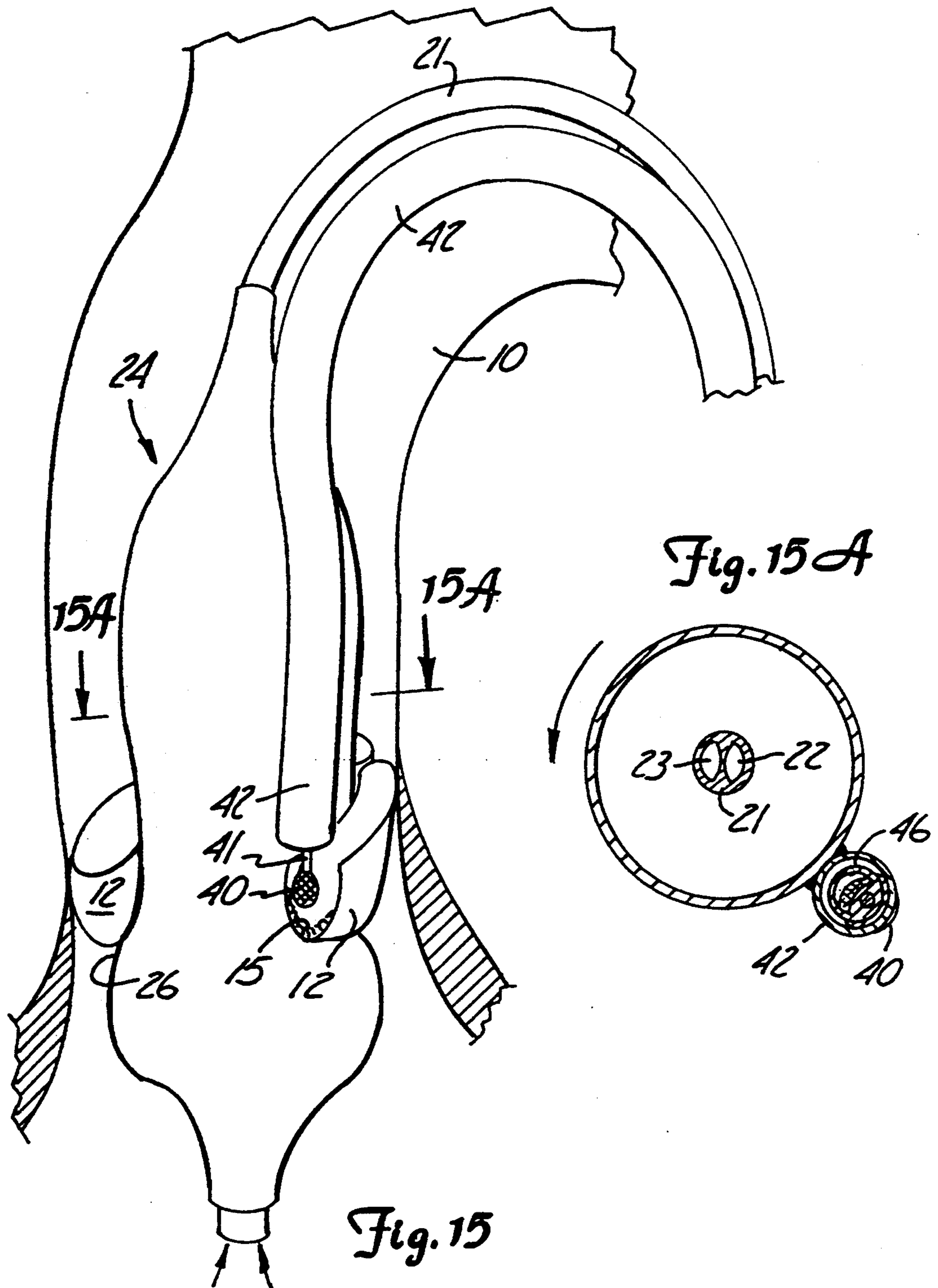


Fig. 14





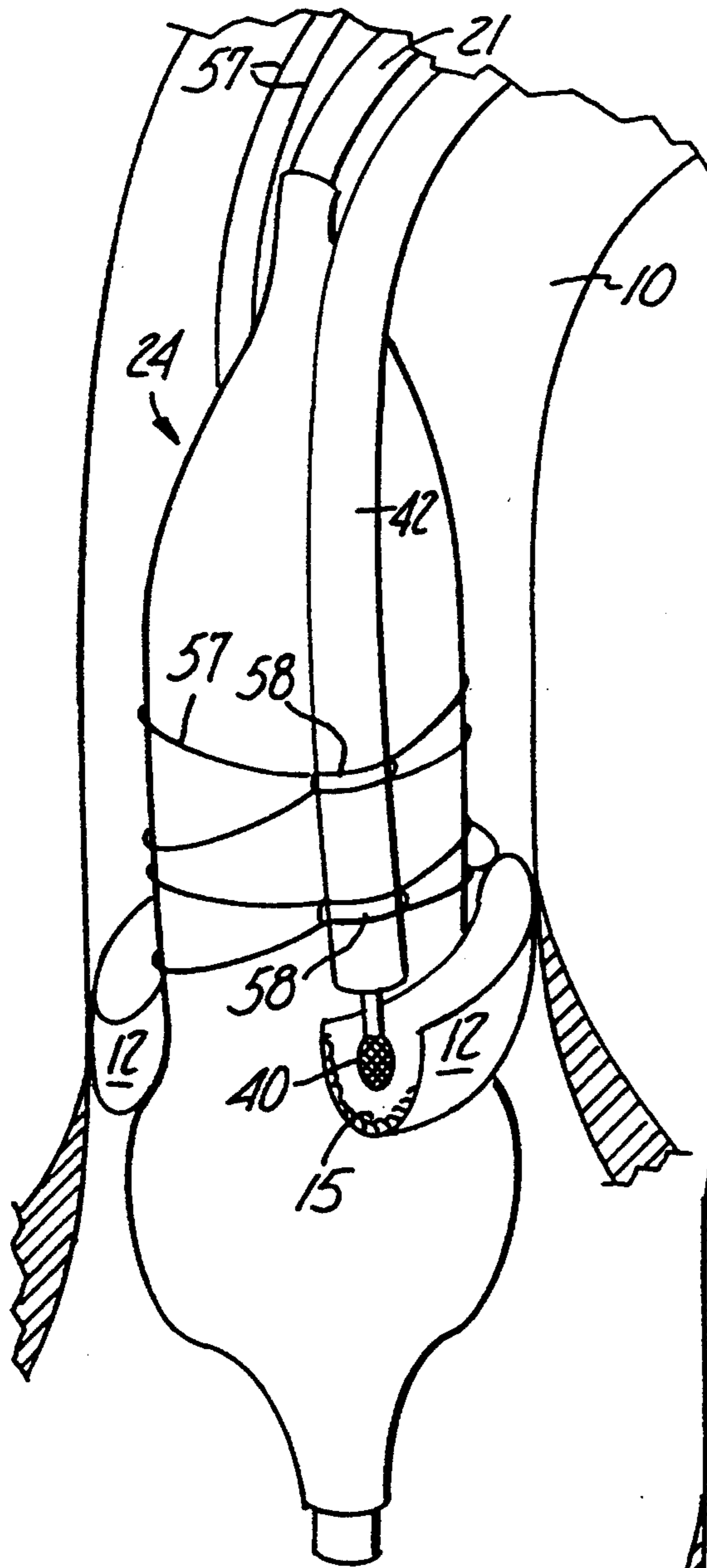


Fig. 16

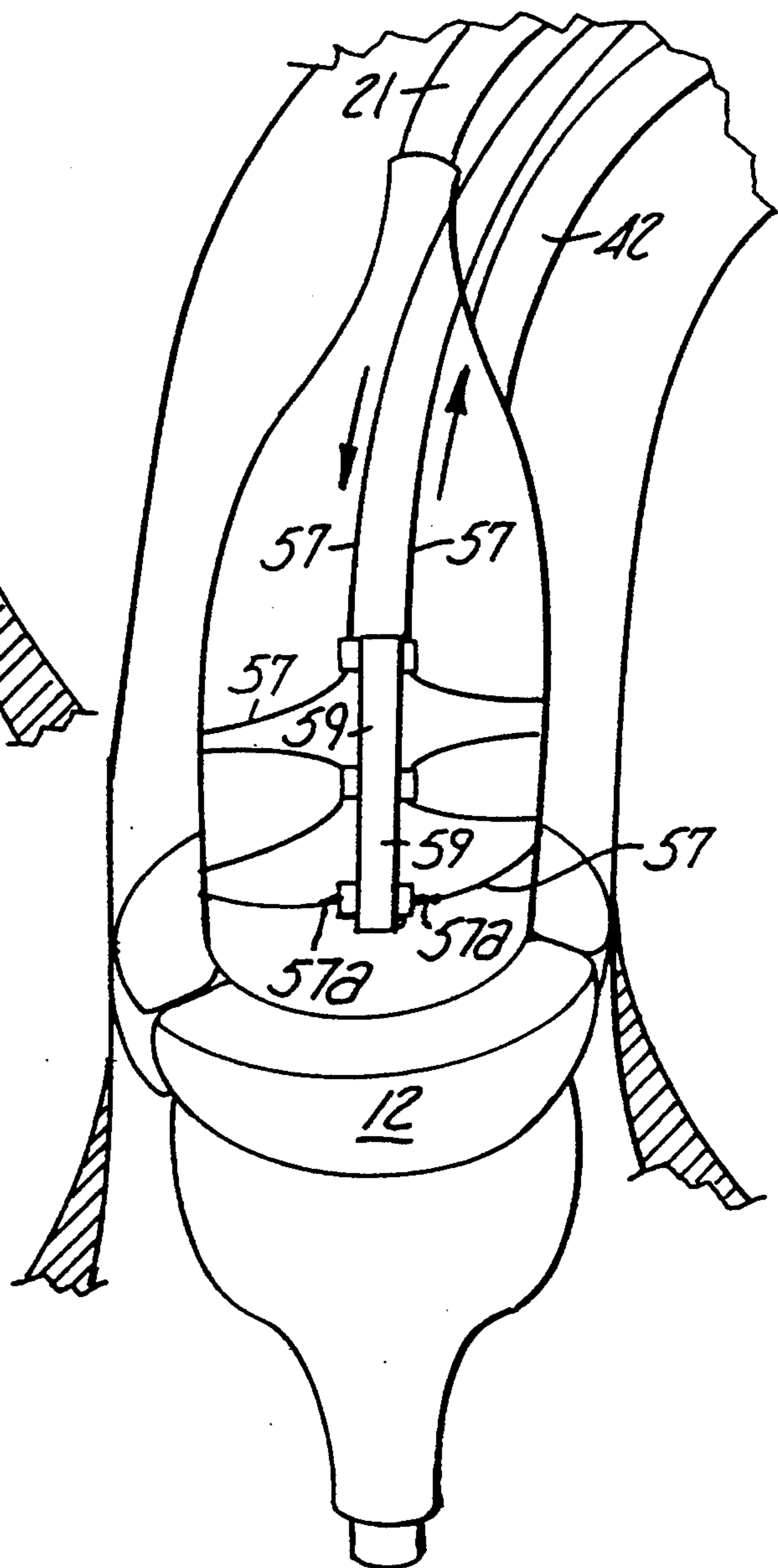
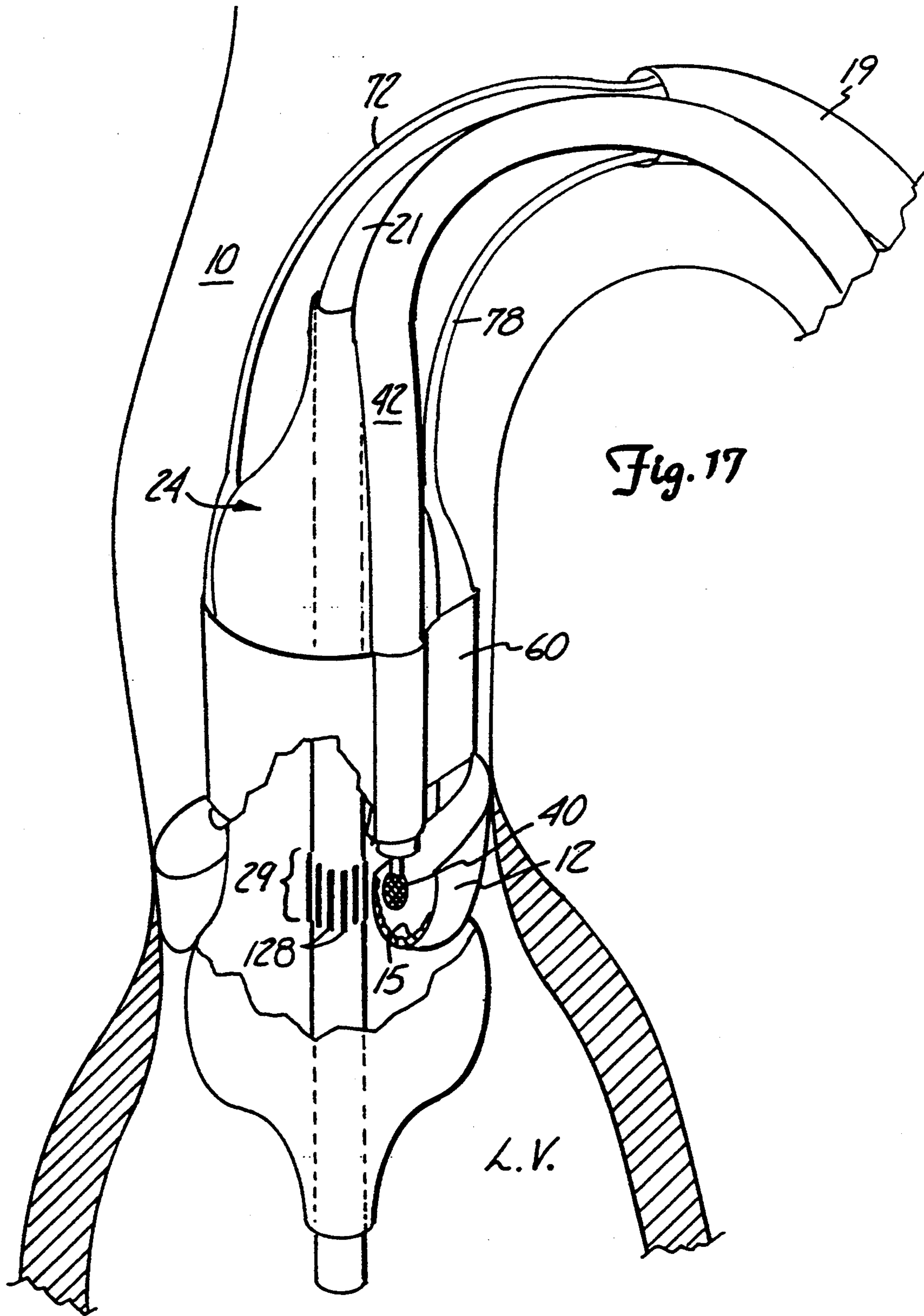


Fig. 16A



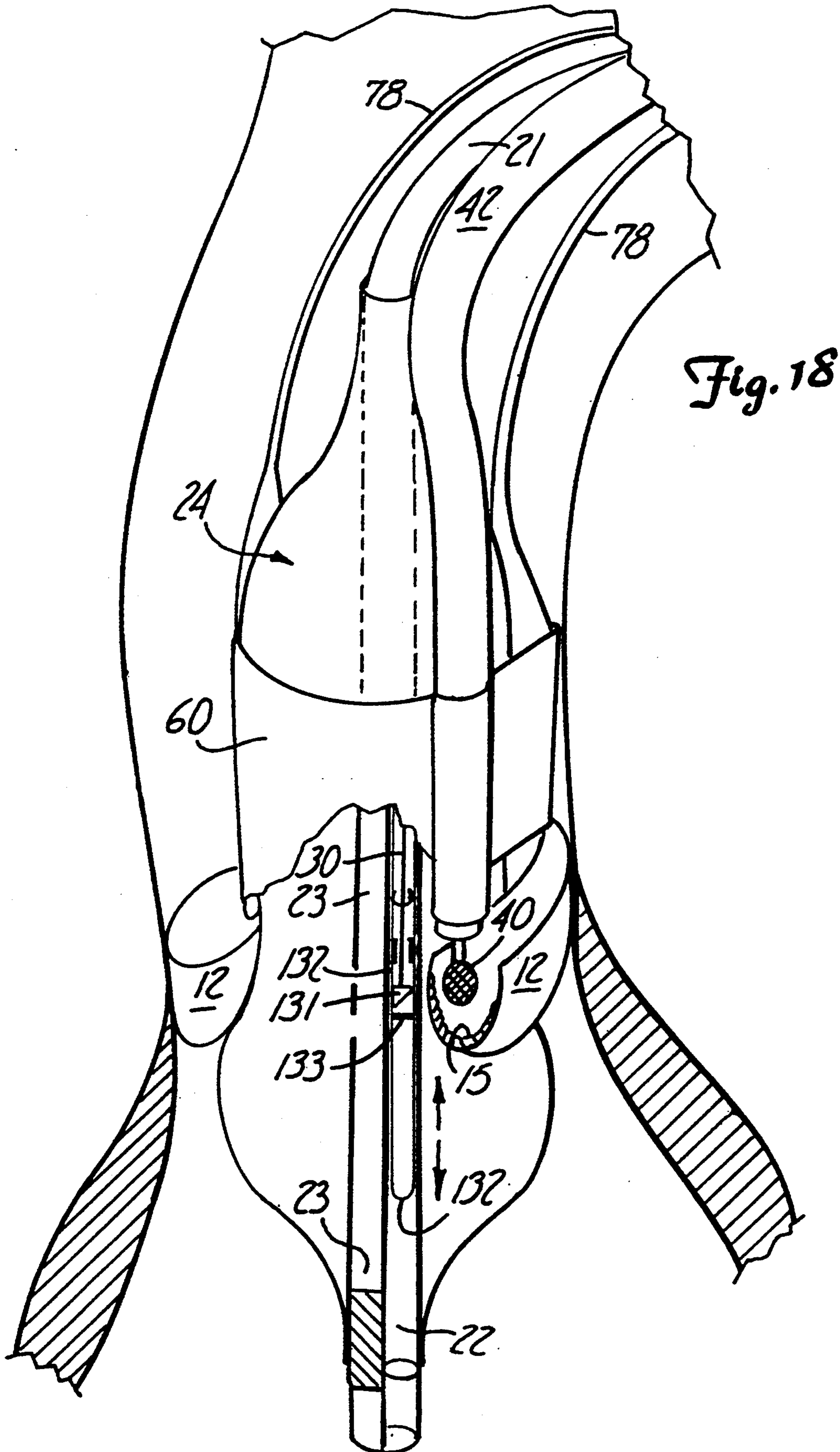


Fig. 18

Fig. 19

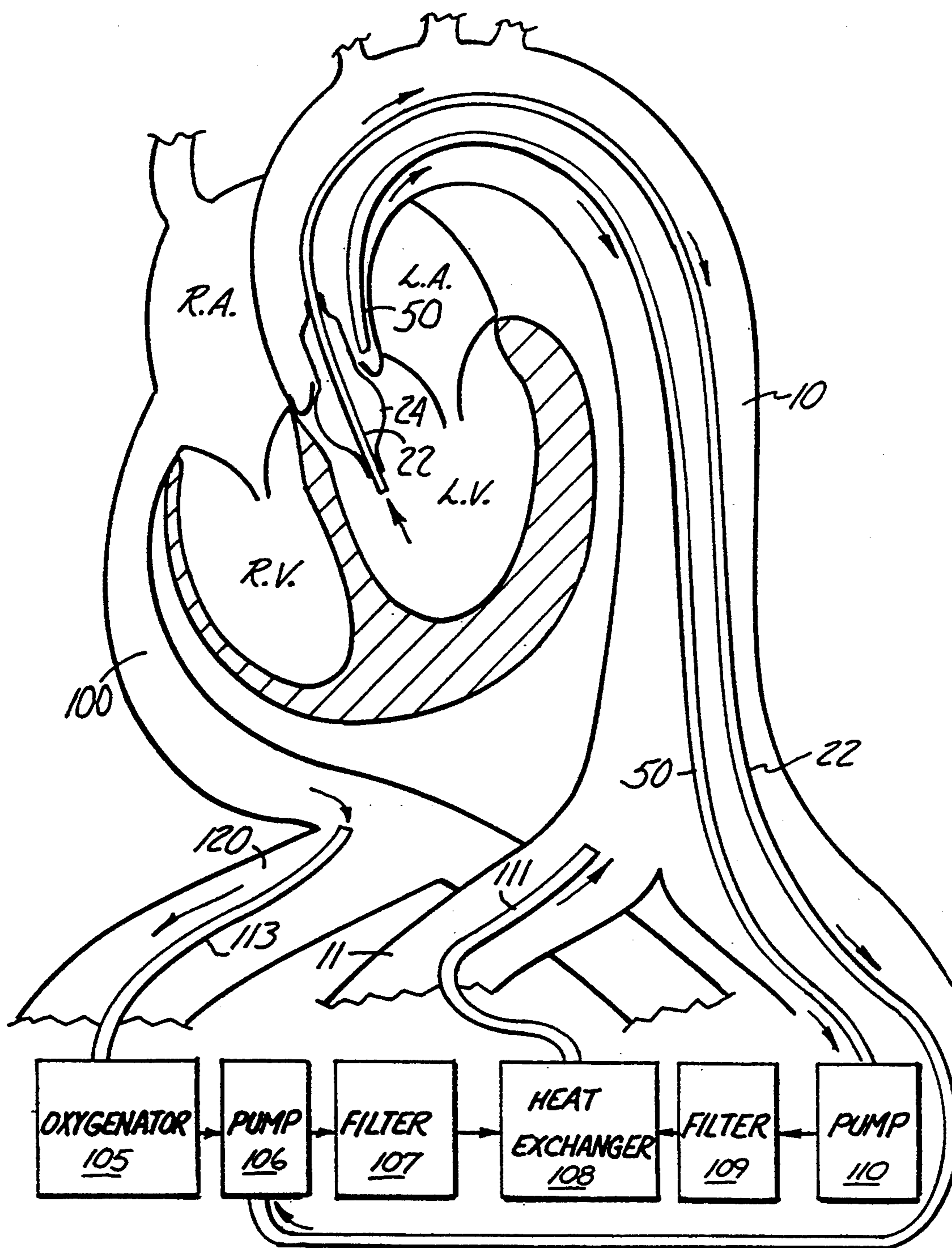


Fig. 20

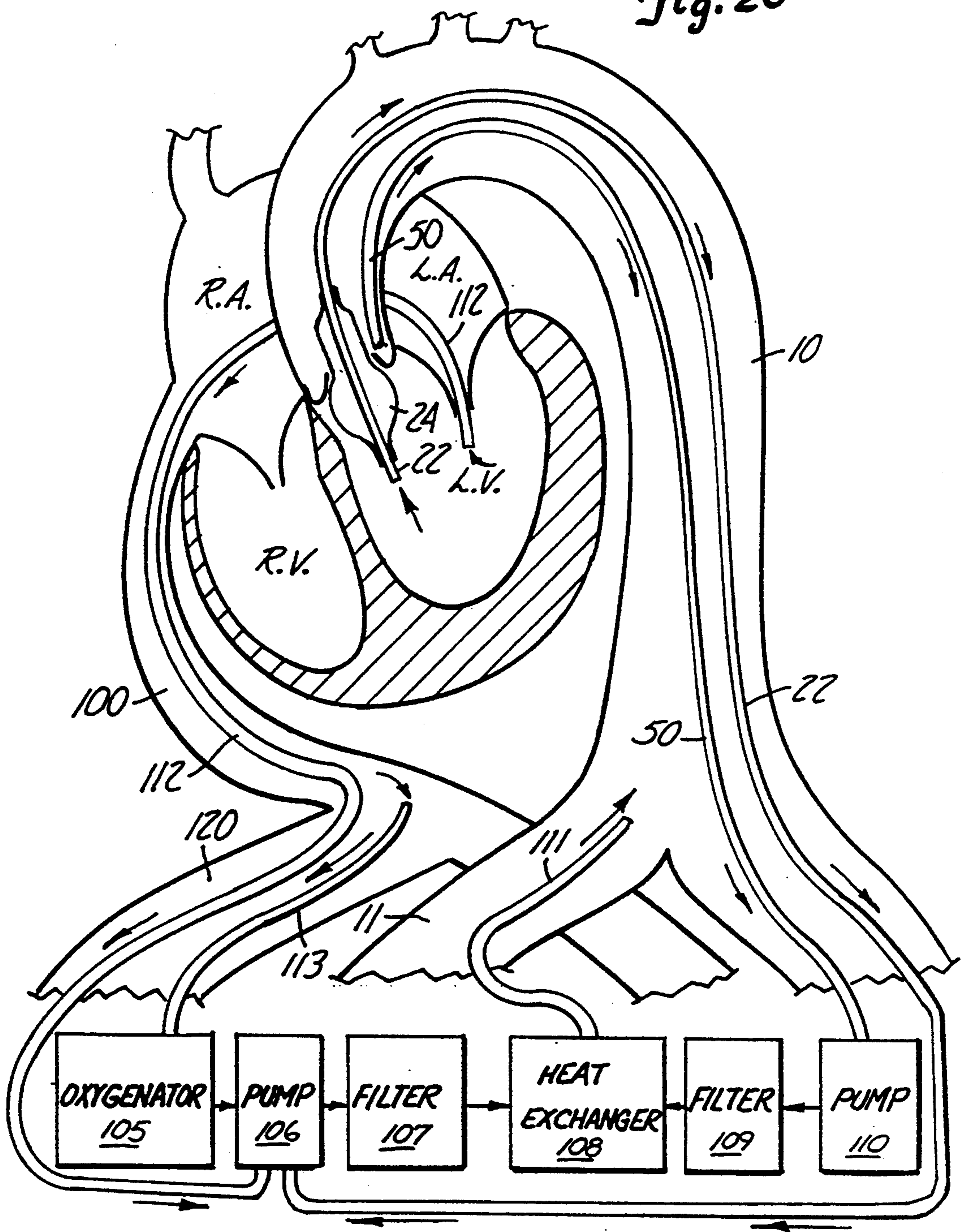


Fig. 21

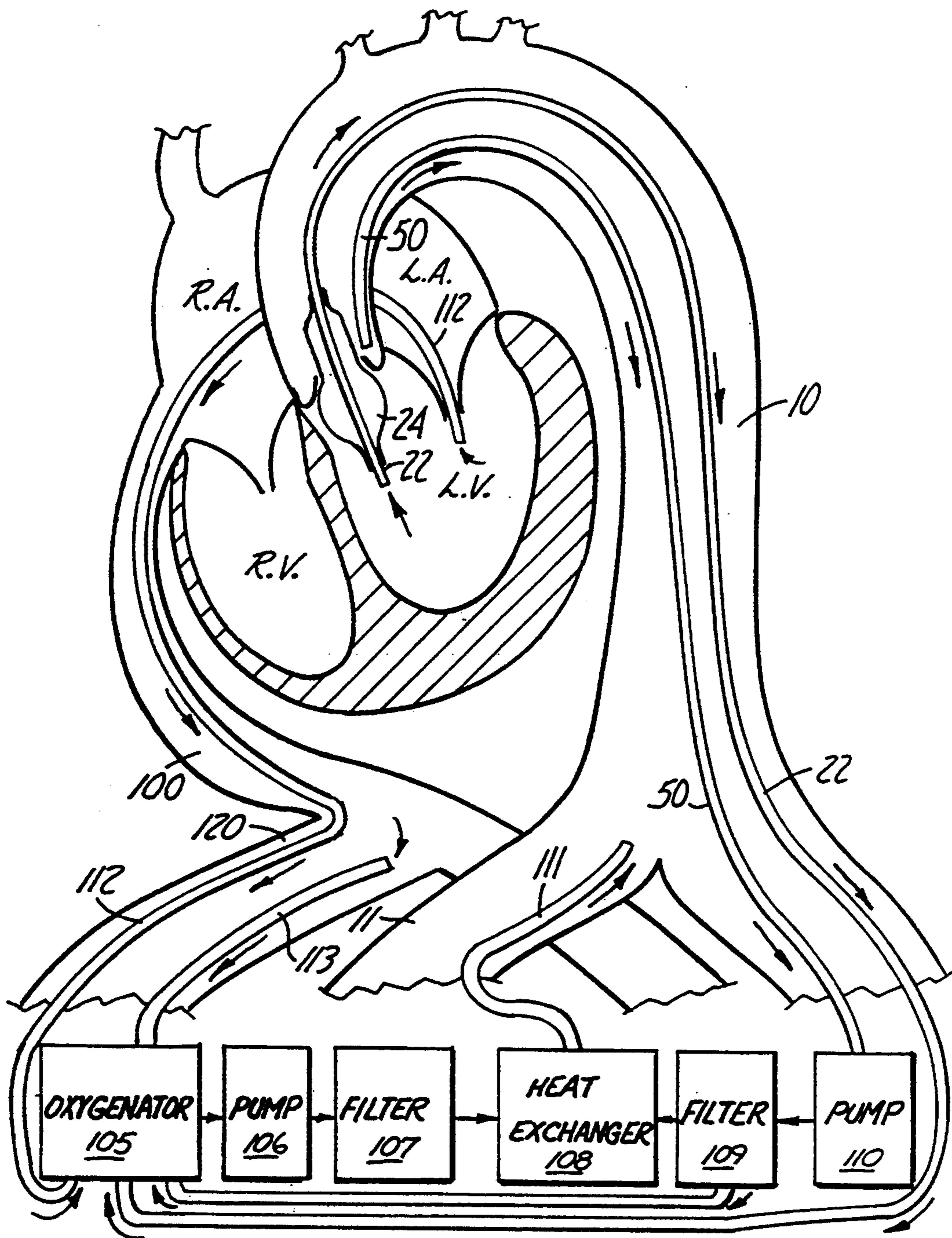


Fig. 22

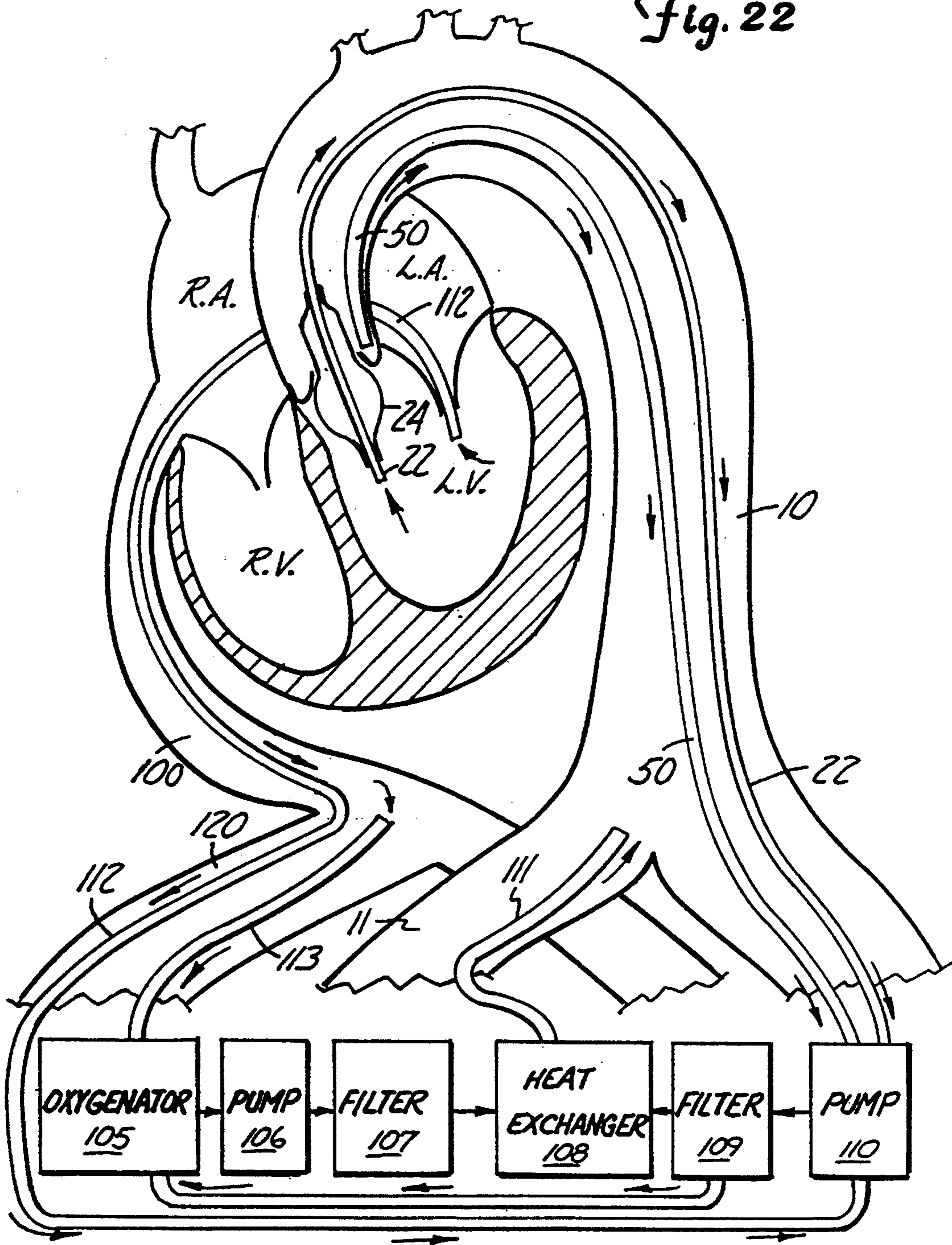


Fig. 23

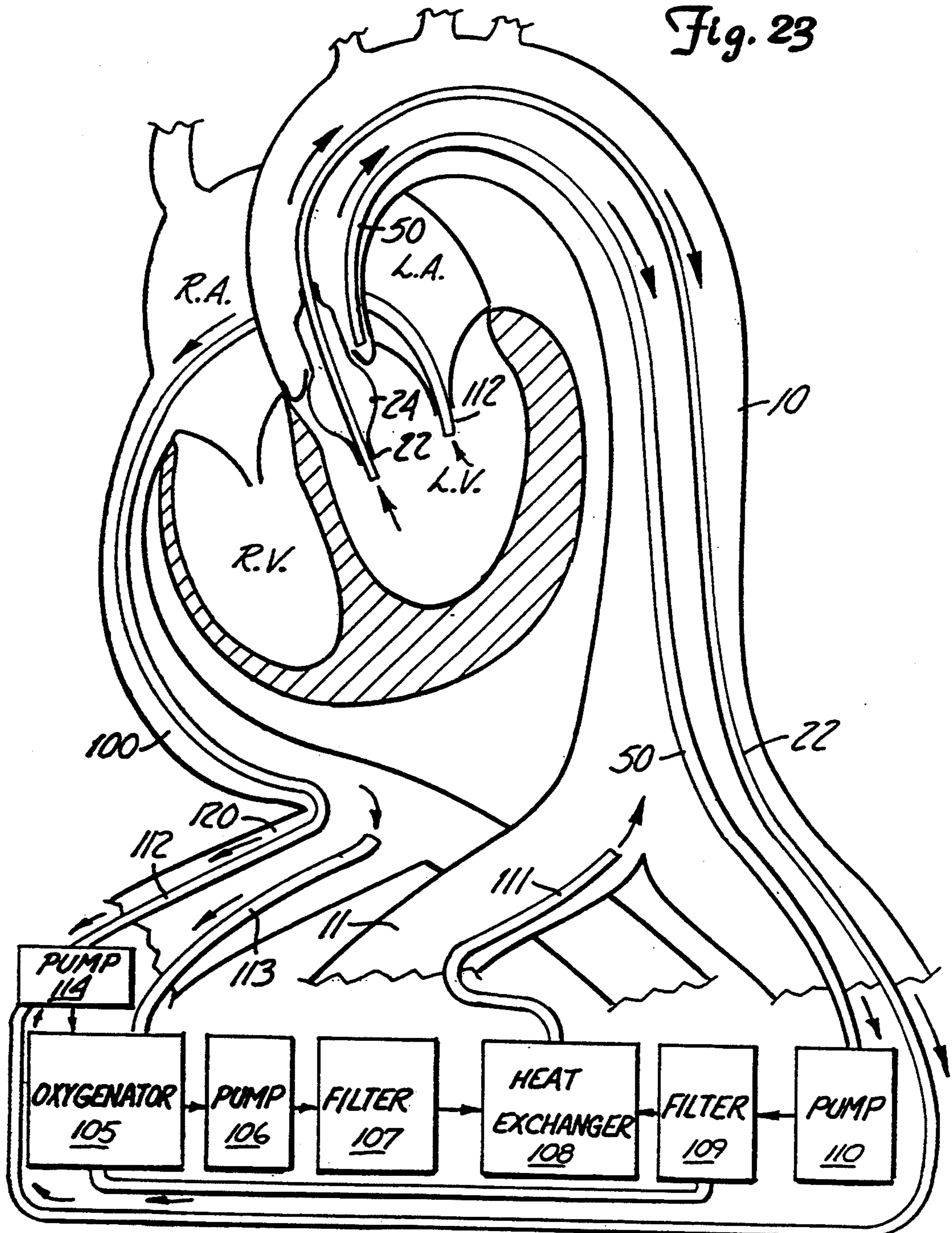
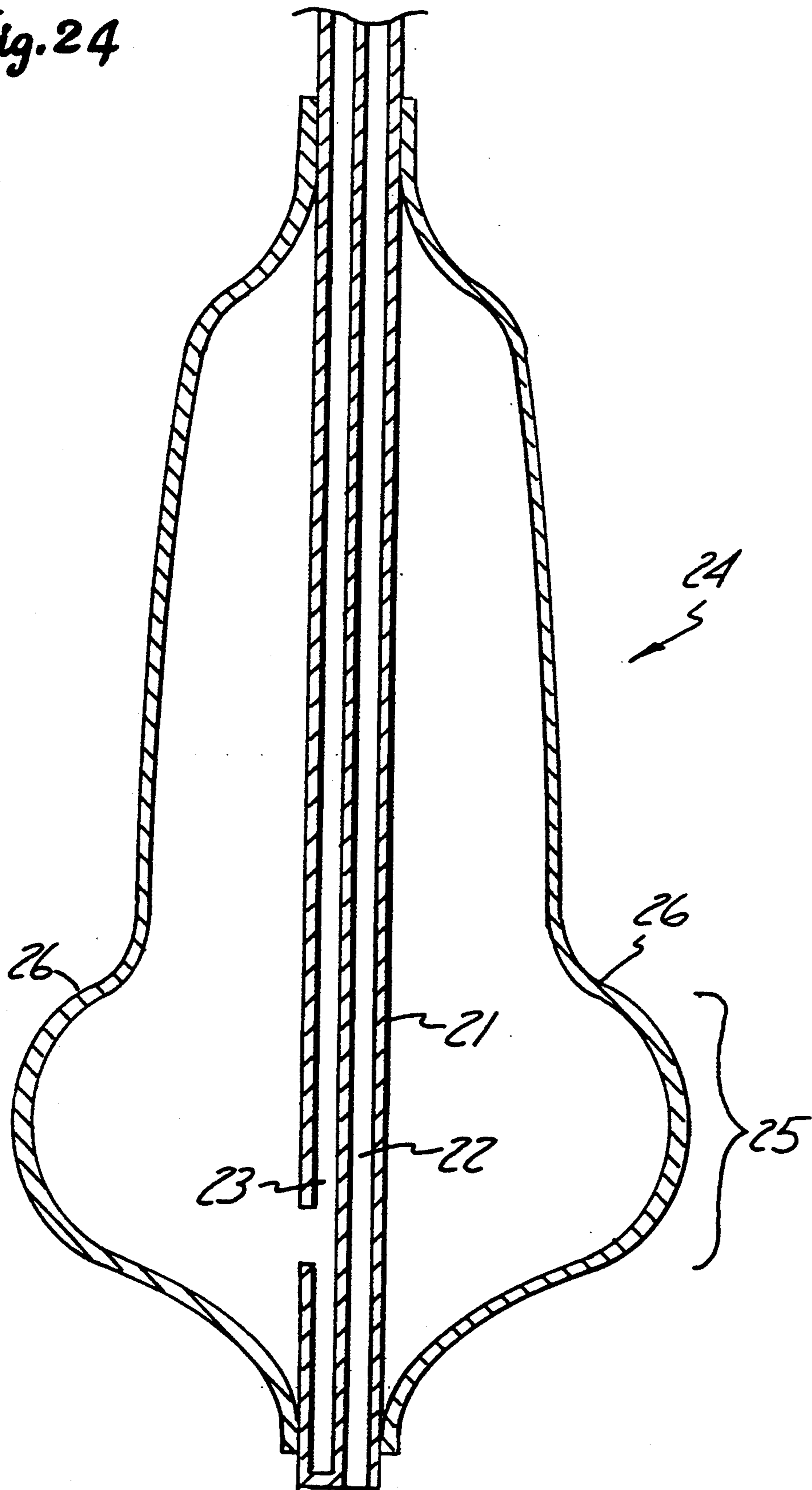
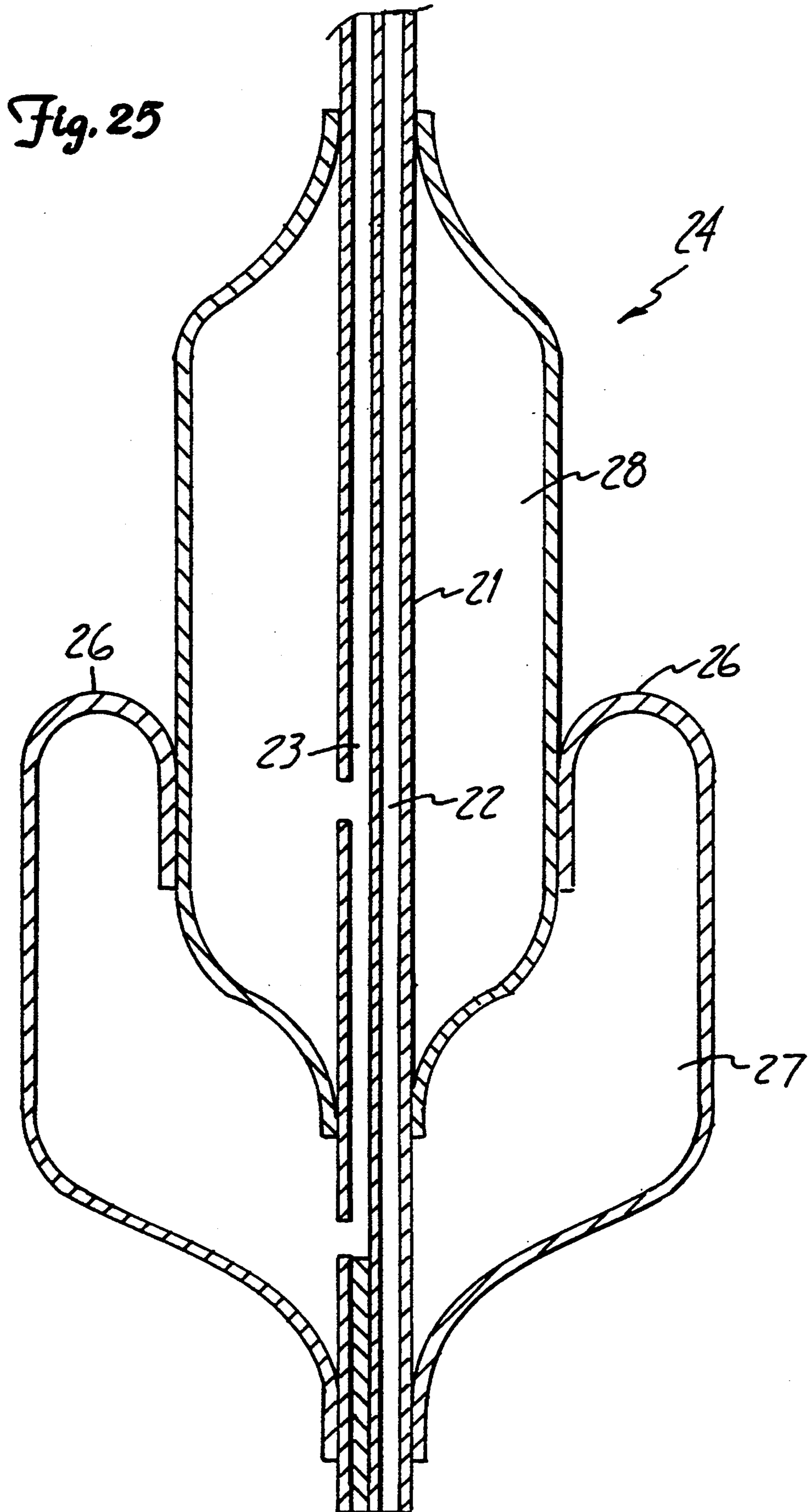


Fig. 24





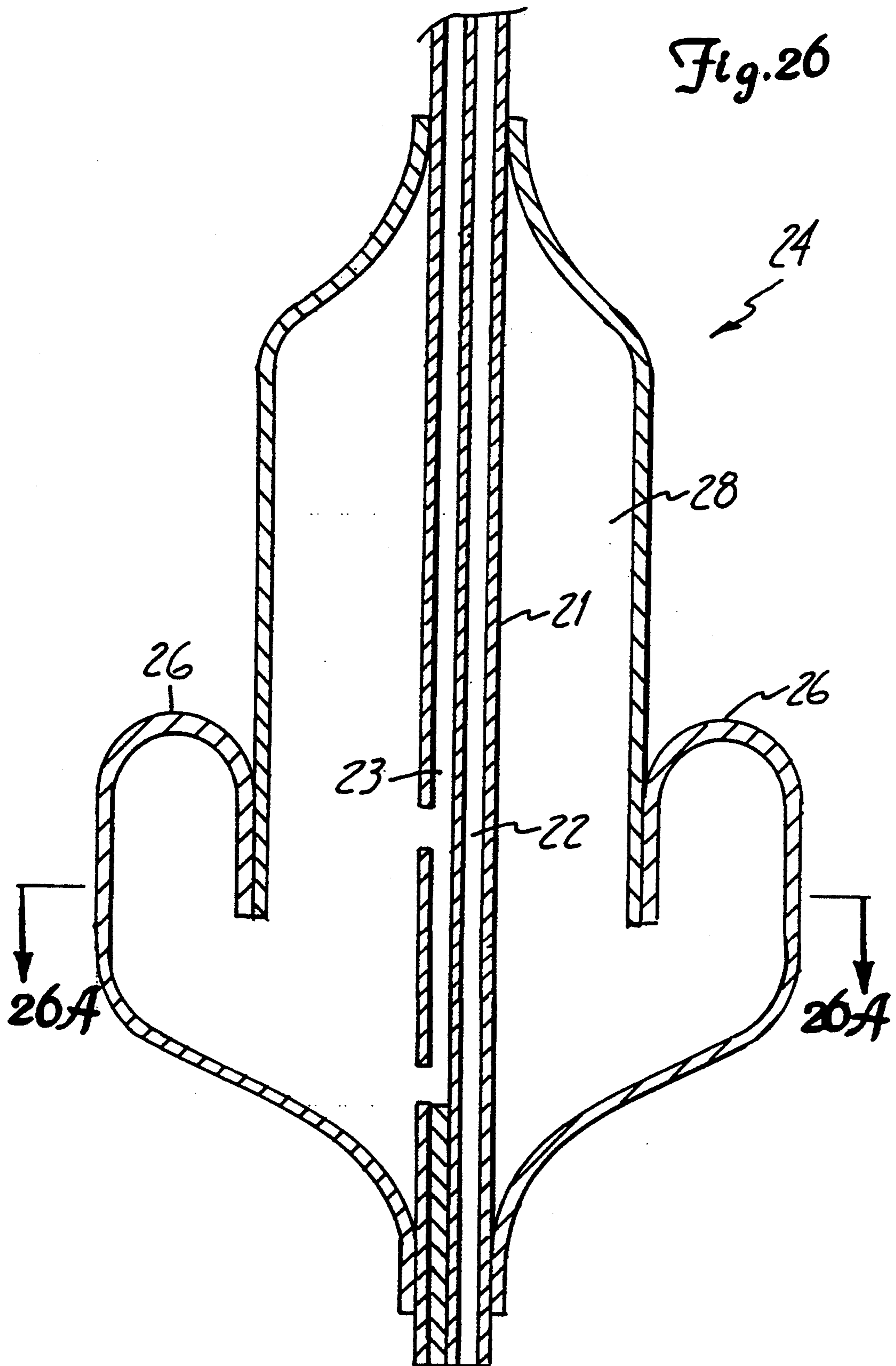
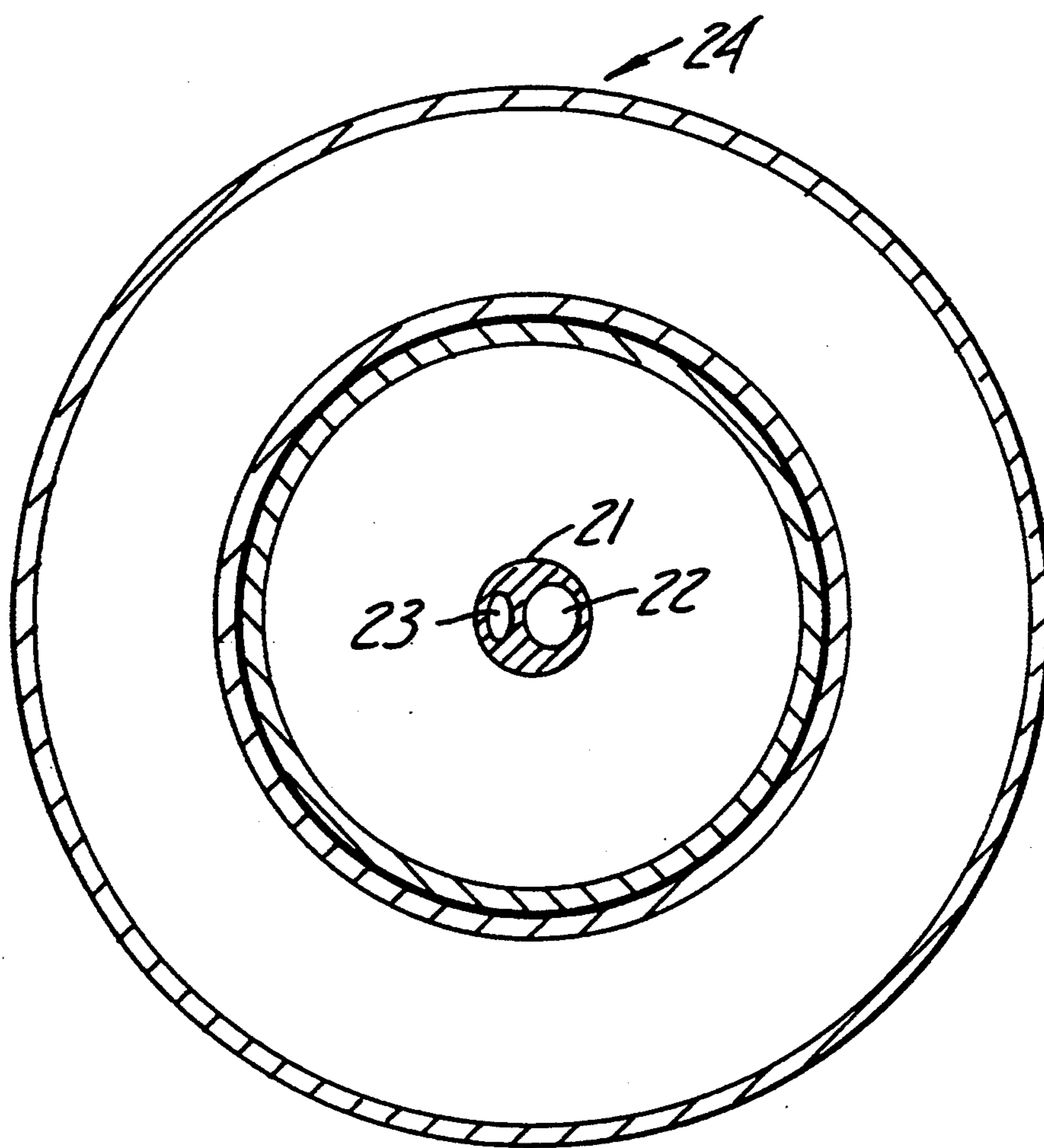


Fig. 26A



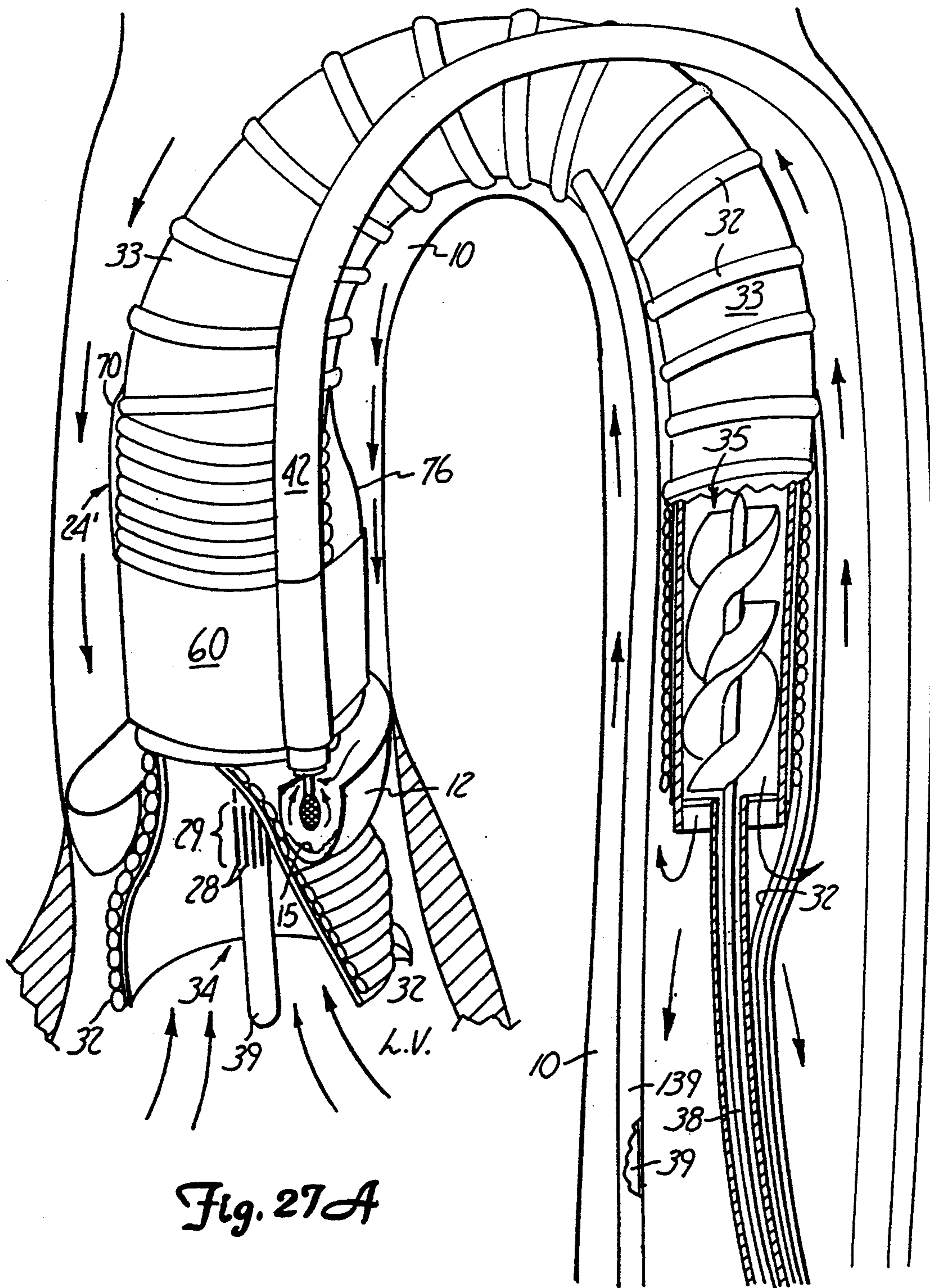


Fig. 27A

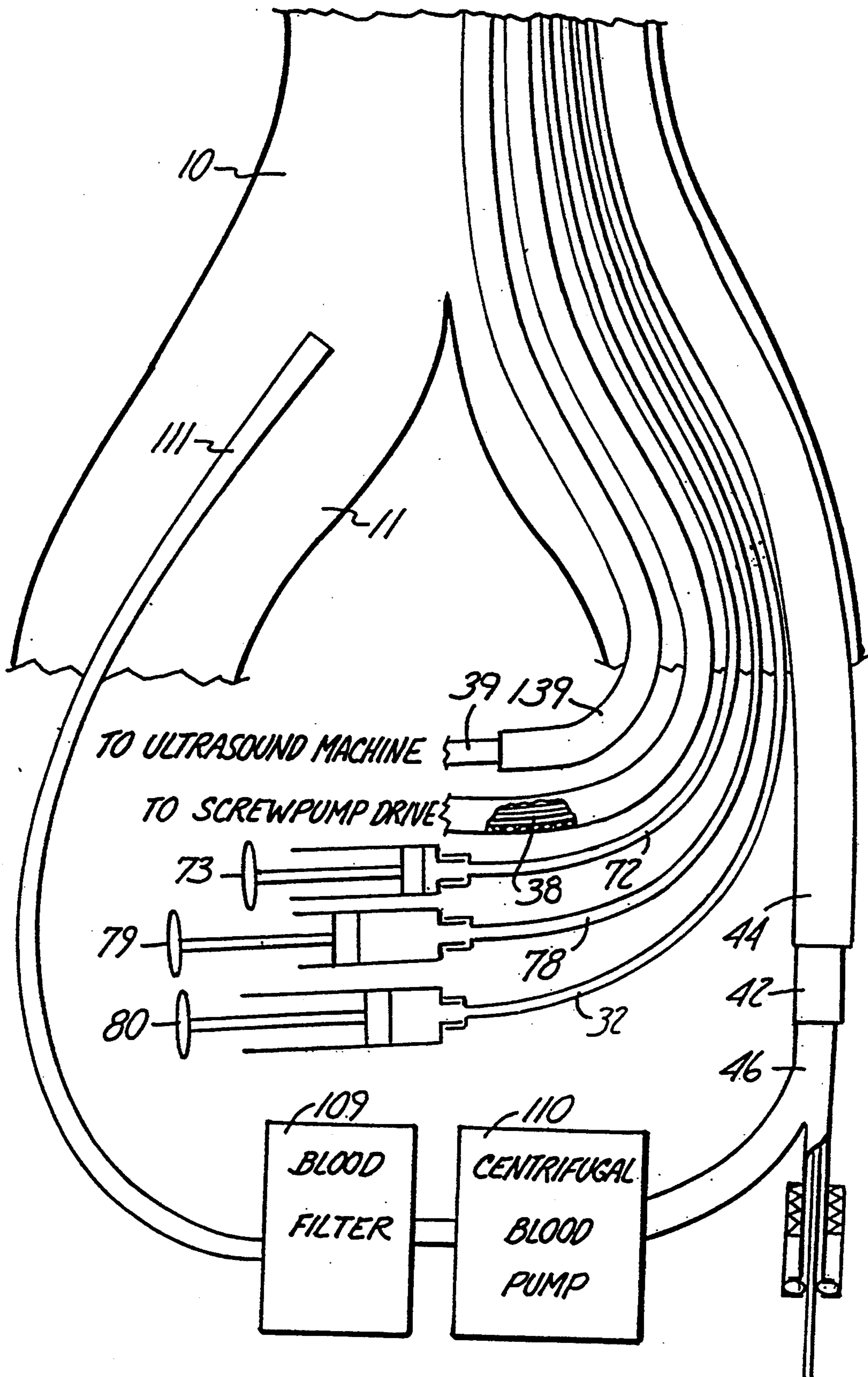


Fig. 27B

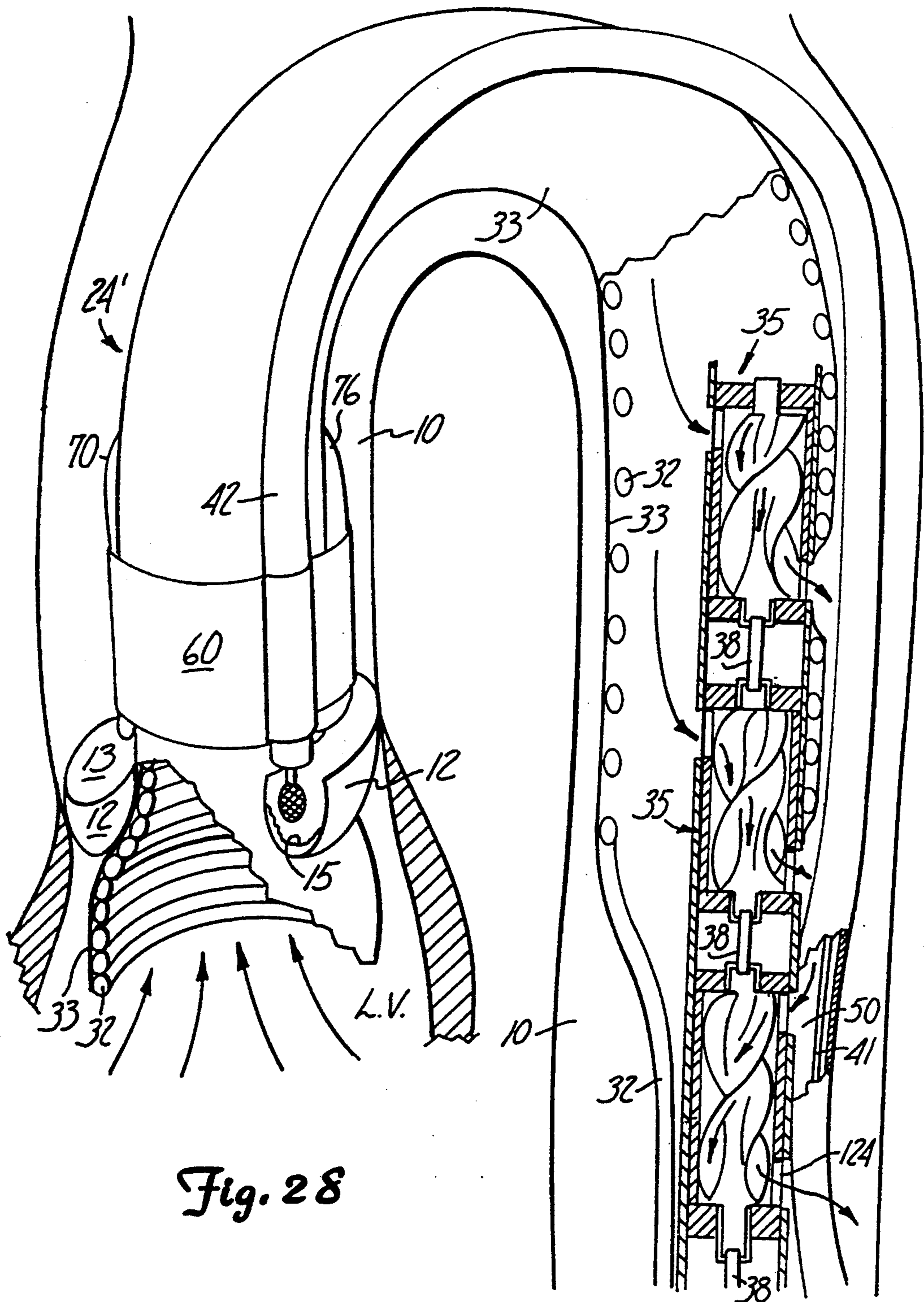


Fig. 28

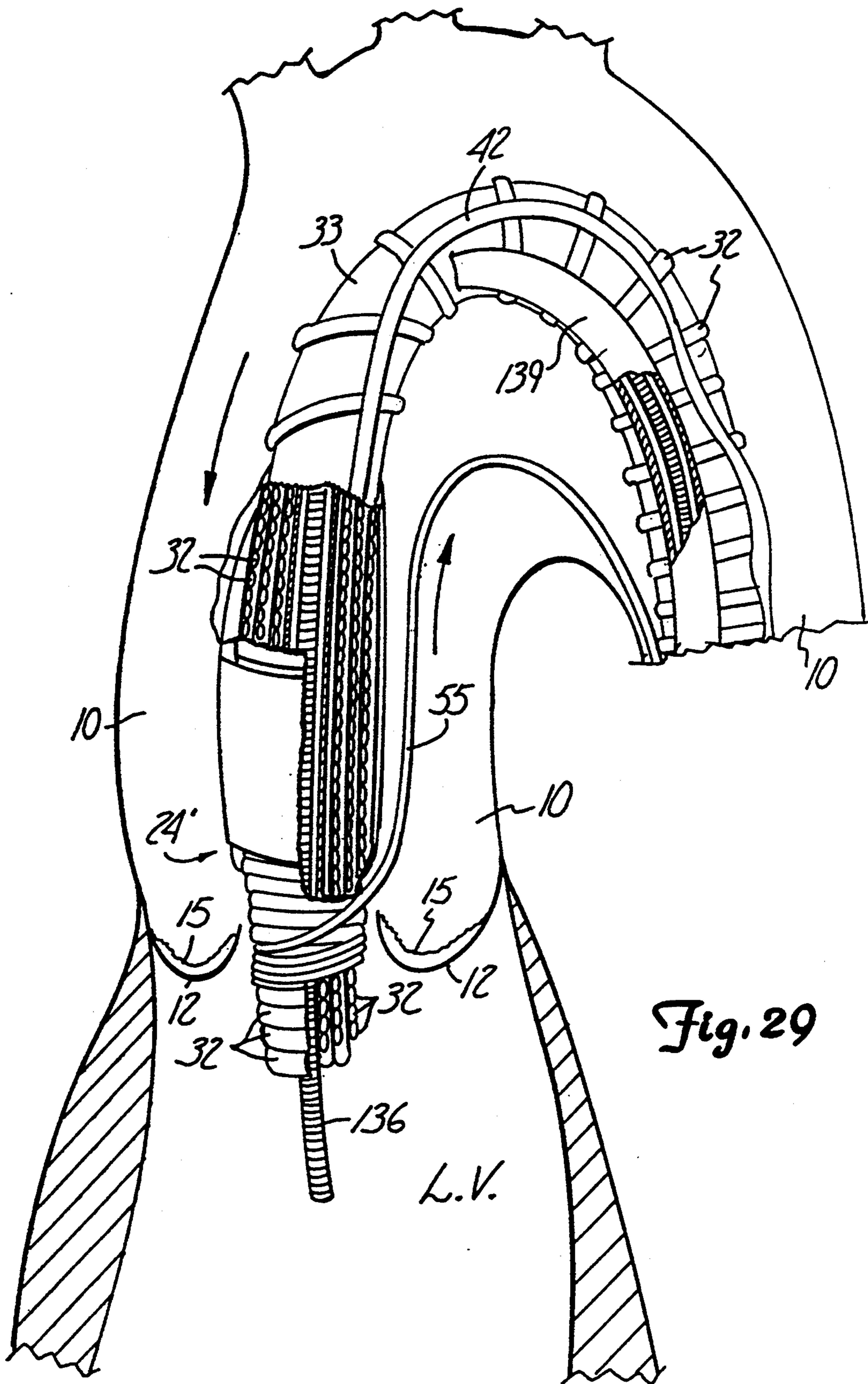
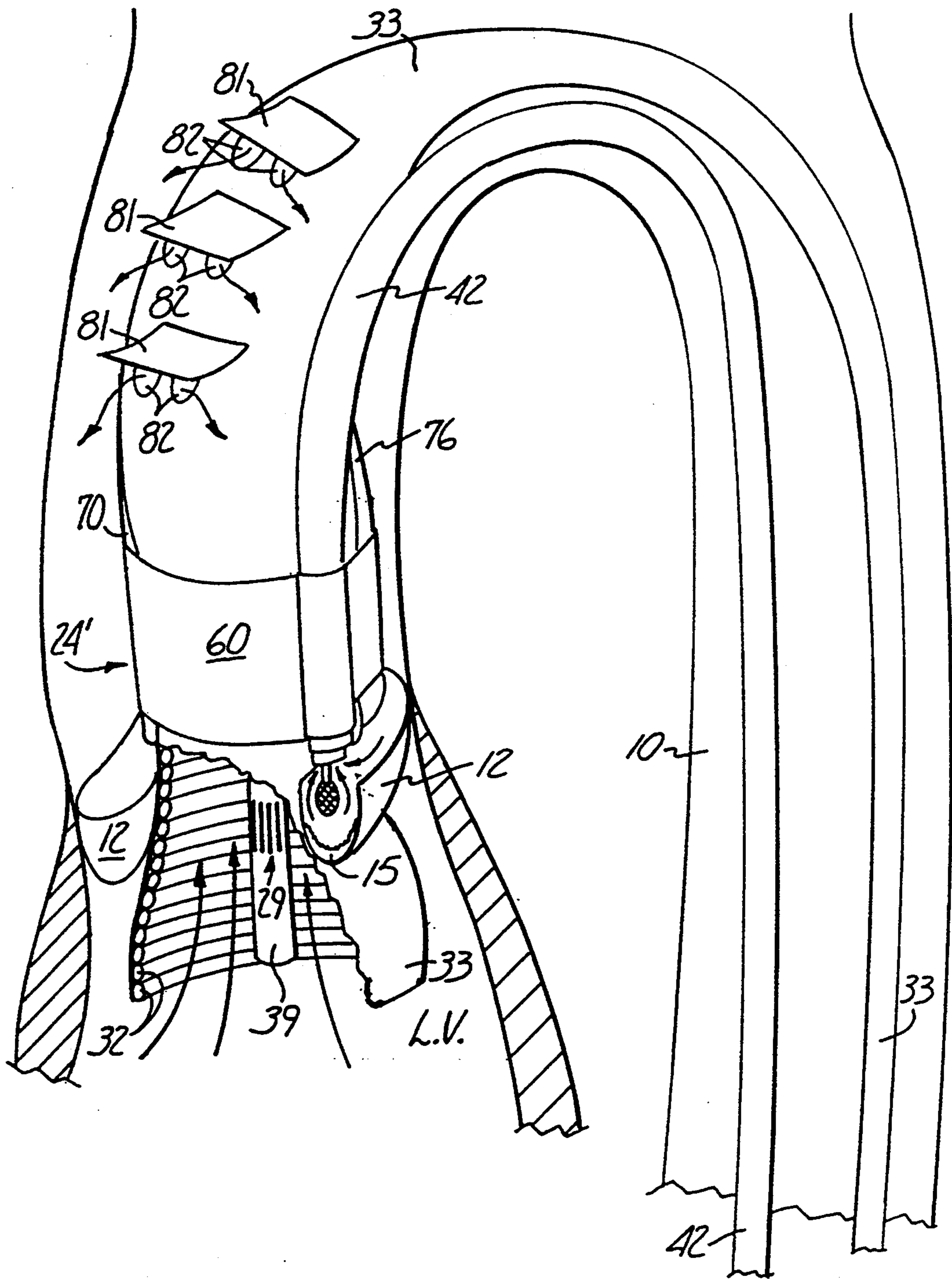


Fig. 29

Fig. 31



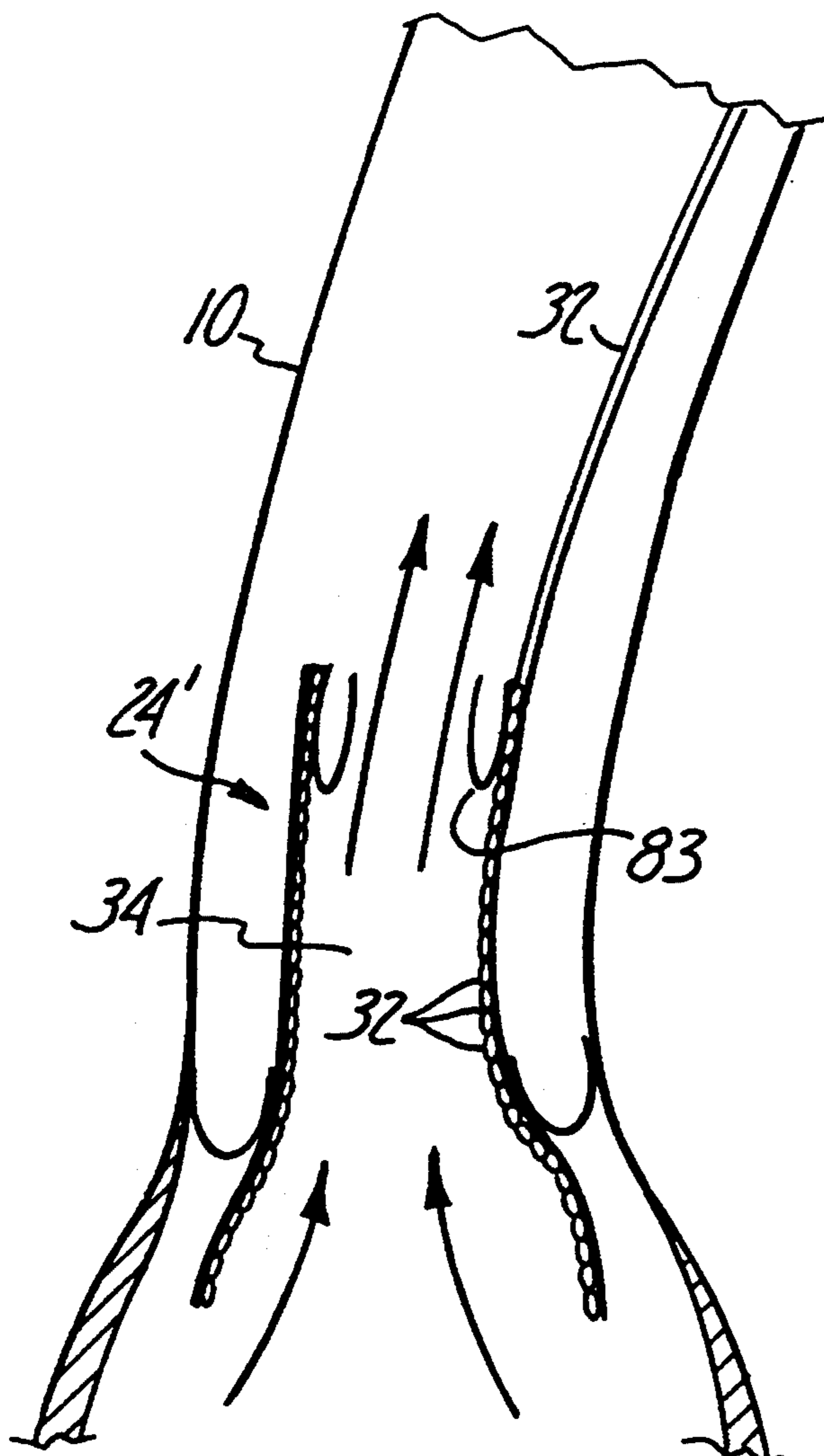


Fig. 32A

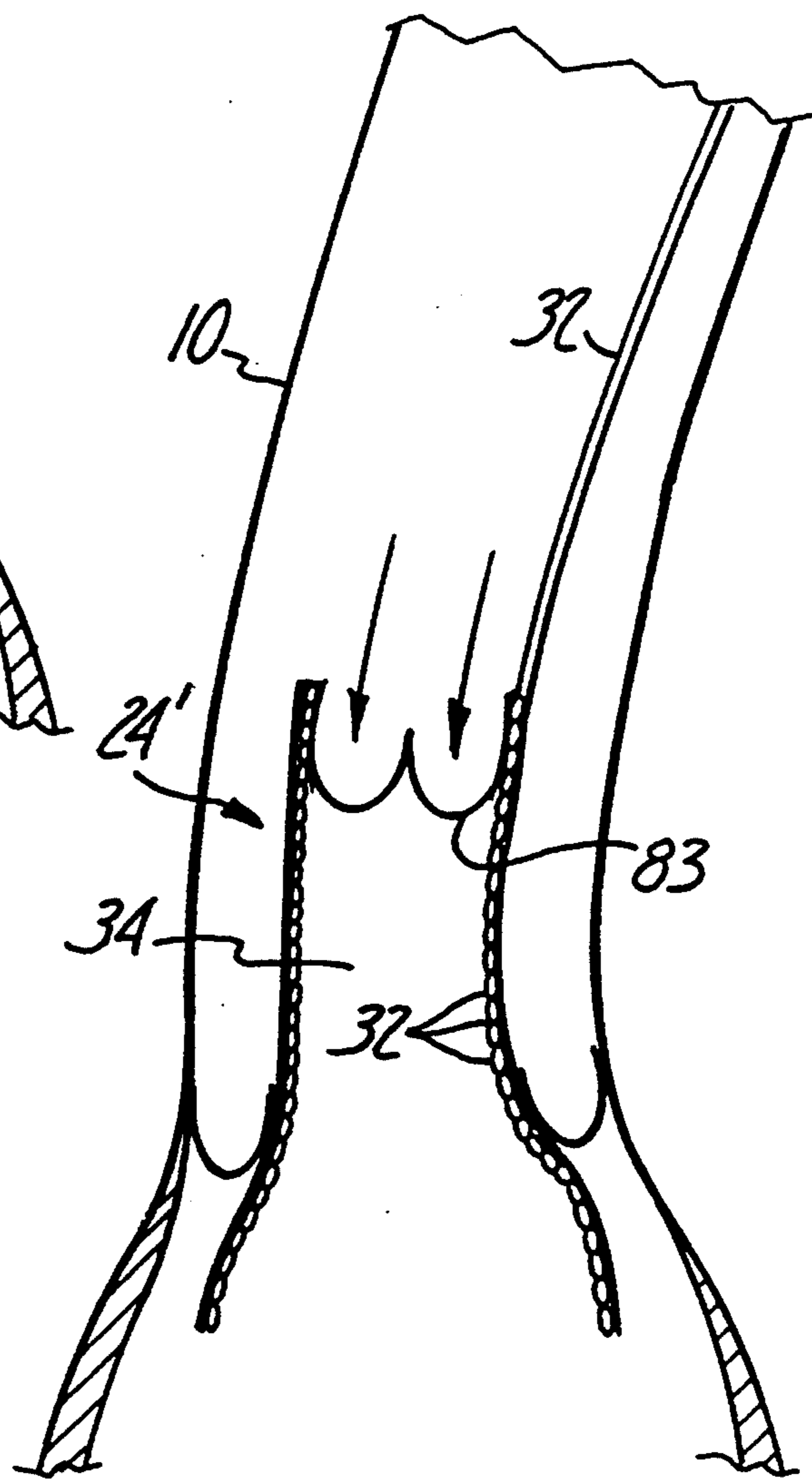


Fig. 32B

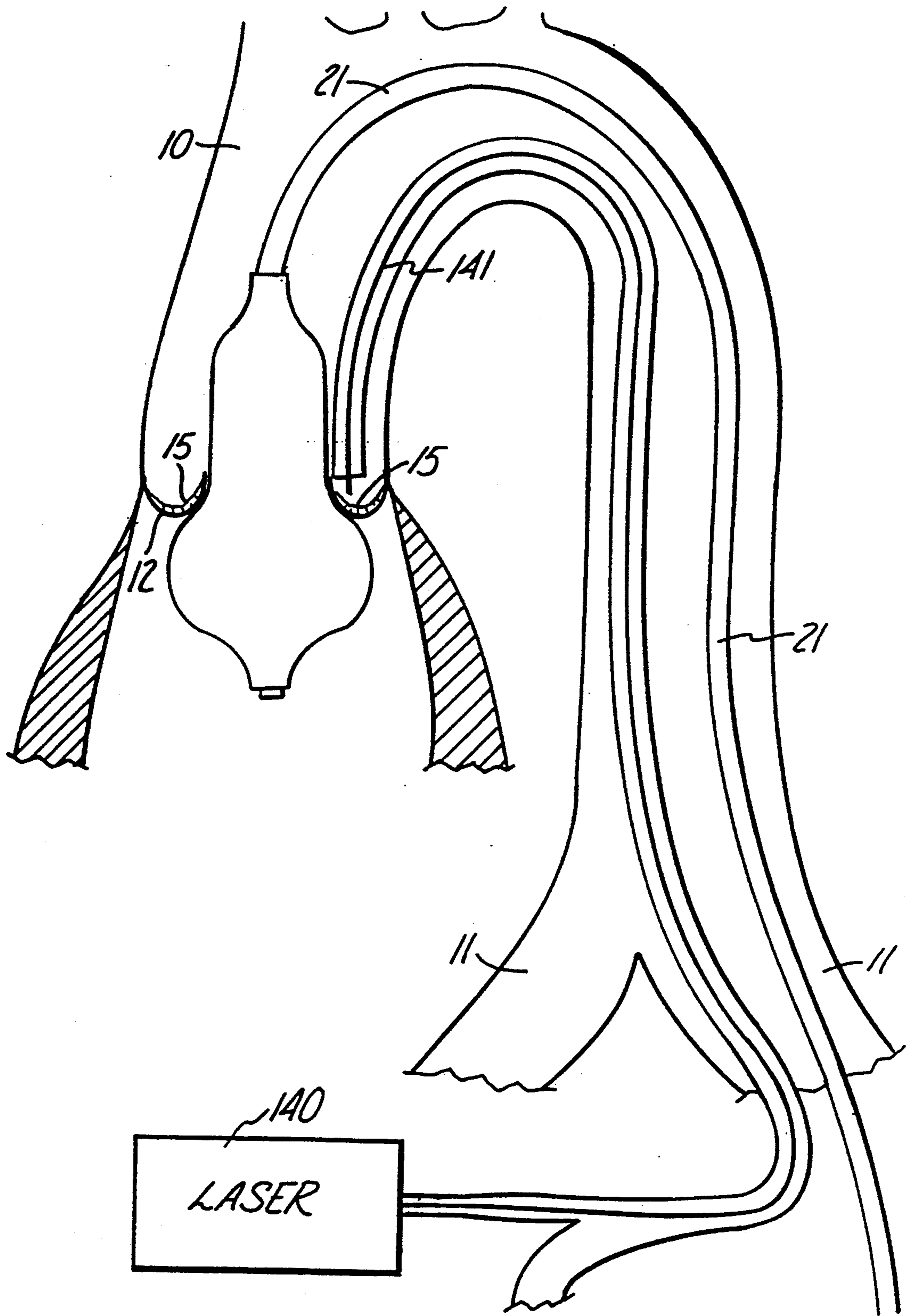


Fig. 33

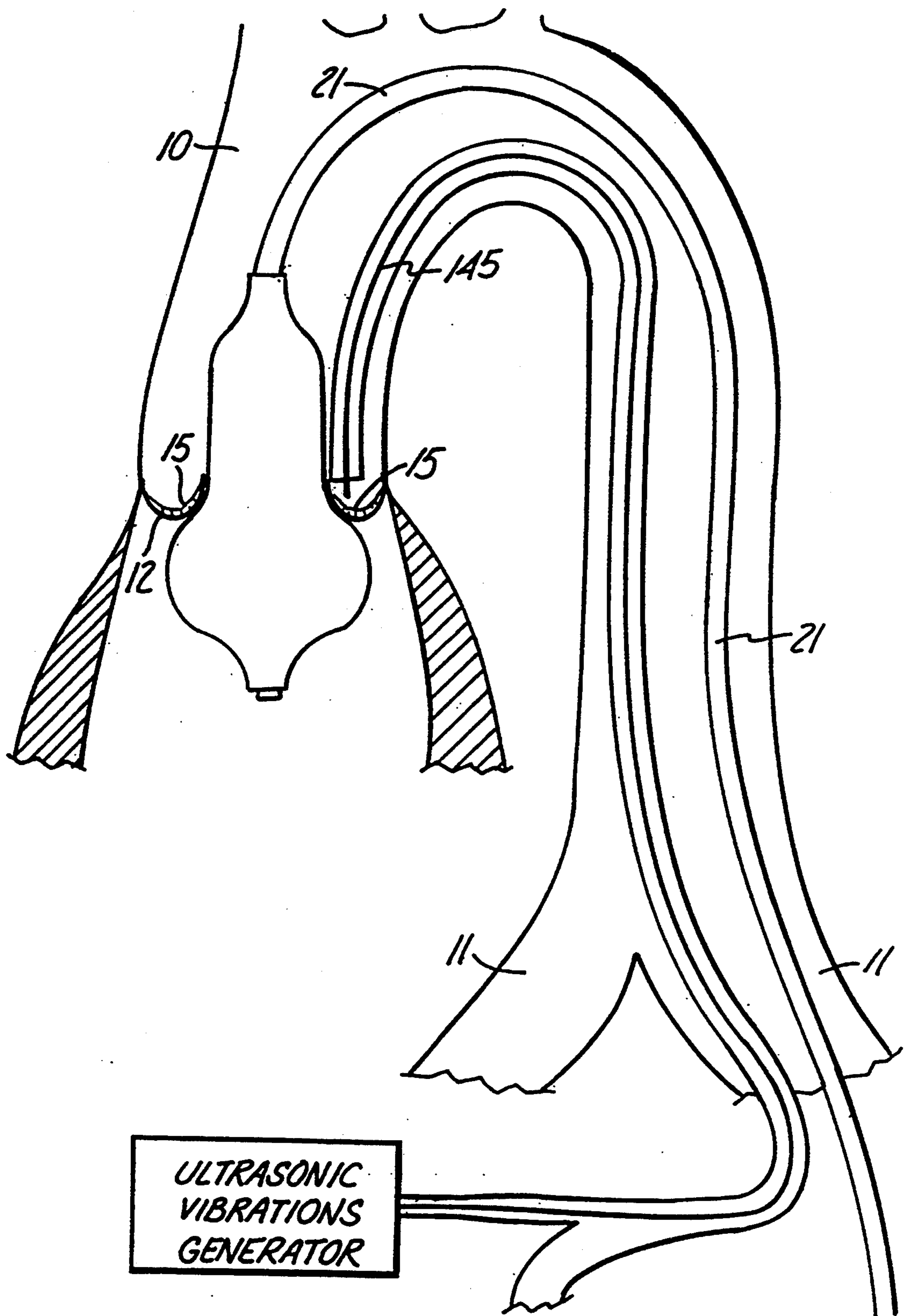


Fig. 34

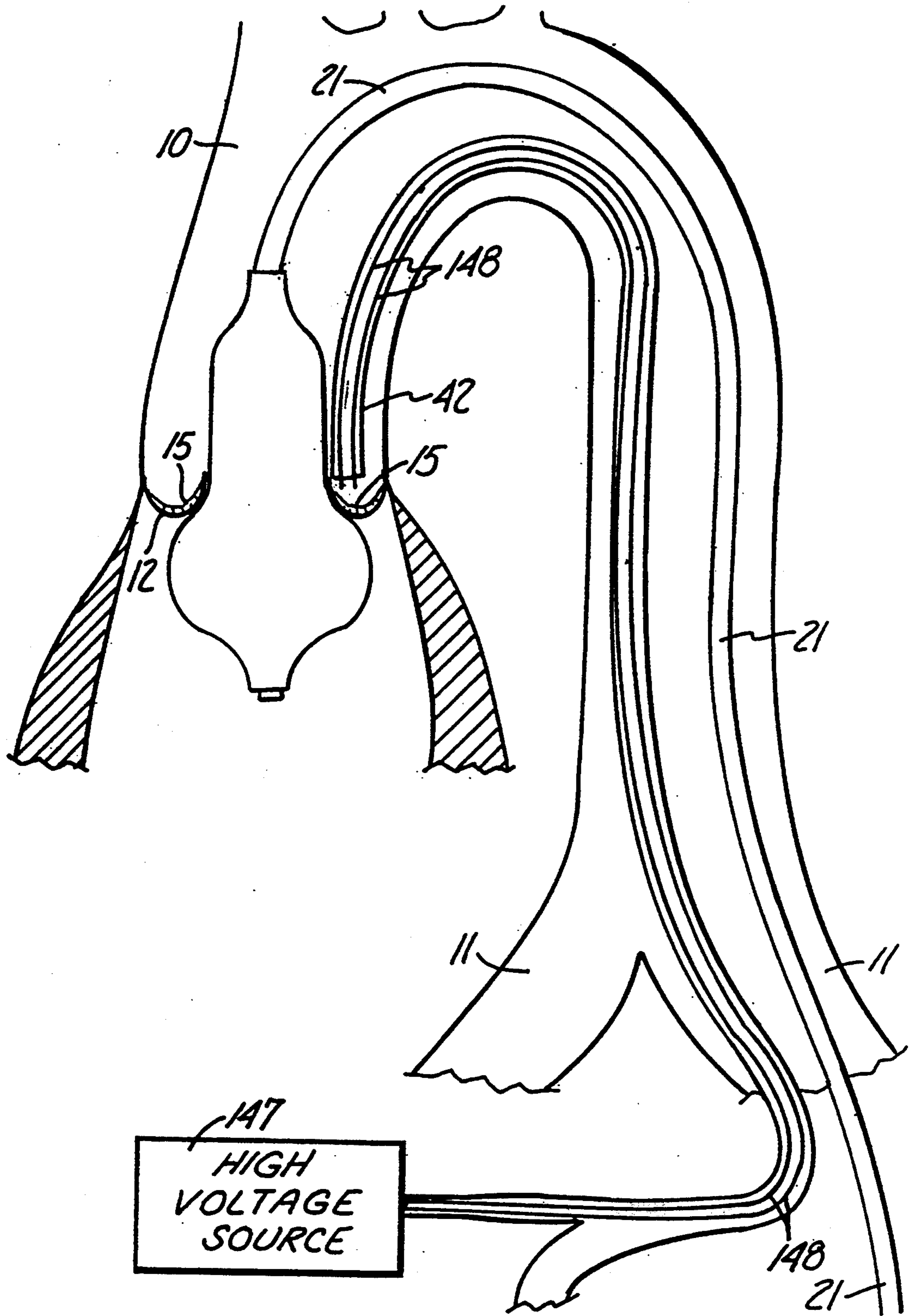


Fig. 35

METHOD AND APPARATUS FOR IN VIVO HEART VALVE DECALCIFICATION

CROSS REFERENCE TO RELATED APPLICATION

This application is a divisional application of U.S. application Ser. No. 07/680,705, filed Apr. 4, 1991 now U.S. Pat. No. 5,295,958.

FIELD OF THE INVENTION

The invention relates to a method and apparatus for removing, in vivo, calcified deposits from heart valves.

BACKGROUND OF THE INVENTION

Calcific aortic stenosis (i.e., the buildup of calcified deposits on the superior surface of the aortic heart valve) accounts for a large percentage of aortic stenosis cases. This condition is characterized by the buildup of calcified nodules on the upper or superior surface of the aortic valve leaflets. These nodules decrease the flexibility of the leaflets, thereby limiting their mobility and capacity to fully open to permit adequate blood flow. Absent anatomic correction, advanced aortic stenosis carries a poor prognosis.

Three techniques have been employed to correct aortic stenosis: valve replacement, intraoperative decalcification (debridement) of the heart valve, and balloon valvuloplasty.

Valve replacement during open heart surgery is currently standard therapy for symptomatic aortic stenosis. Ten year survival rates for isolated aortic valve replacement are generally very good, even in elderly patients. However, this technique requires that the patient be healthy enough to undergo open heart surgery. The operative mortality for this procedure, particularly among the elderly, is also significant—variously reported at between about 5% and 12%. In addition, a patient receiving a replacement valve typically must take anticoagulation drugs for the rest of his or her life—not all patients are capable of doing this. Moreover, some patients have an aortic root that is not large enough to easily accommodate conventional replacement valves. Thus, there are a significant number of patients for whom valve replacement is either impossible, impractical, or undesirable.

Intraoperative mechanical debridement (decalcification) of the aortic valve to treat aortic stenosis was successfully used for many years prior to the advent of mechanical replacement valves. In this technique, the aorta is entered surgically (as in a valve replacement procedure) but rather than replace the valve the surgeon manually removes the calcified deposits, using suitable surgical tools. The debridement techniques, although for some time completely forsaken in favor of valve replacement procedures, has enjoyed some recent revival, particularly for patients having a small aortic root and/or contraindications for anticoagulation therapy. In addition to mechanical tools, recently ultrasonic debridement has also been demonstrated to be effective to remove calcific deposits. Nevertheless, these techniques still require the patient to be healthy enough to survive and recuperate from thoracic surgery, and involve all of the costs and risks attendant with such surgery.

The third technique for correcting aortic stenosis involves percutaneous balloon aortic valvuloplasty (BAV). In this procedure, an inflatable balloon catheter

is advanced to the aortic valve and inflated to compress and fracture the calcified nodules in an attempt to increase leaflet mobility. Although this procedure eliminates many of the risks and disadvantages attendant with the preceding two techniques, restenosis is very common within one year, limiting the technique's usefulness to temporarily mitigating symptoms for those patients who are poor surgical candidates or refuse surgery.

SUMMARY OF THE INVENTION

The invention provides a method and apparatus for in vivo removal of calcified deposits from an aortic valve. The apparatus includes an anchoring balloon catheter fixatable across the aortic valve, a tool for removing the deposits, and attachment means for securing the tool with respect to the anchoring balloon and the aortic valve.

The attachment means preferably includes means for positioning the deposit removal tool with respect to the anchoring balloon. In one embodiment the distal end of a guiding catheter is secured to the anchoring balloon, and positioning of the tool is accomplished by selectively moving the distal end of the guiding catheter about the anchoring balloon and by moving the tool around within the guiding catheter.

One embodiment for securing the guiding catheter with respect to the anchoring balloon while allowing selective movement of the guiding catheter employs a circumferential band having first and second ends respectively attached to the anchoring balloon, with the distal end of the guiding catheter attached to an intermediate portion of the band. Positioning balloons are interposed between the circumferential band and the anchoring balloon. The positioning balloons work in concert, so that as one balloon is inflated, the other is deflated, thereby changing the relative position of the intermediate portion of the band and the associated distal end of the guiding catheter. Thus, when a first of the balloons is being inflated (with the second balloon being simultaneously deflated), the distal end of the guiding catheter will move clockwise about the anchoring balloon, and when the second balloon is being inflated (with the first balloon being simultaneously deflated), the distal end of the guiding catheter will move counterclockwise about the anchoring balloon.

The deposit removal tool may be positioned within the guiding catheter by providing a coaxial positioning catheter within the guiding catheter. The positioning catheter preferably includes an off-center lumen in which the elongated shaft of the removal tool is closely received. Thus, by rotating the positioning catheter within the guiding catheter, the position of the removal tool can be selectively controlled.

The removal tool may comprise any effective device, including any one of a variety of rotatable cutting, scraping or abrading devices, an ultrasonic vibrations generator or a wire capable of conveying ultrasonic vibrations and being connected to an ultrasonic vibrations generator, an optical fiber connected to a laser outside of the body, a pair of electrodes connected to a high voltage source outside of the body, or any other suitable device.

In a modified embodiment of the invention, the anchoring balloon catheter utilized in the invention comprises an inflatable tube that has a proximal, generally straight portion, and a distal, helically coiled portion.

The turns of the helical coil may be spaced from one another slightly, or successive turns may abut one another. Means may also be provided for securing the turns of the coil to one another, such as by providing an outer or inner skin to which the turns adhere.

The method of the invention involves removing, in vivo, deposits from an aortic valve's superior surface. The method comprises the steps of advancing an anchoring balloon catheter through the aorta and positioning it across the aortic valve, inflating the anchoring balloon to fixate it with respect to the aorta and aortic valve, and then operating a deposit removal tool secured to the anchoring balloon to remove the deposits.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view in partial cross-section of the apparatus of the invention fixated in the aortic valve of a heart;

FIG. 2 is a perspective view in partial cross-section similar to FIG. 1 with one of the valve leaflets removed for clarity and with the guiding catheter shown in a moved position;

FIG. 3 is a cross-section of FIG. 1 taken along line 3—3 thereof;

FIG. 4 is a cross-sectional view similar to FIG. 3 shown in a moved position;

FIG. 5 is another cross-sectional view similar to FIG. 3 showing a second moved position; FIG. 6 is a cross-sectional broken-away view of a modified embodiment of the invention;

FIG. 7 is a cross-sectional view of FIG. 6 taken along line 7—7 thereof;

FIG. 8 is a cross-sectional view of FIG. 6 taken along line 8—8 thereof;

FIG. 9 is a somewhat schematic representation of another embodiment of the apparatus of the invention in the process of being introduced into a patient;

FIG. 9A is a cross-sectional view of FIG. 9, taken along line 9A—9A thereof;

FIG. 10 is a view similar to FIG. 9 after the guiding catheter has been introduced into the otherwise flaccid sheath;

FIGS. 10A and 10B are cross-sectional views of FIG. 10, taken respectively across lines 10A—10A and 10B—10B thereof;

FIG. 11 is a view similar to FIG. 9 after the tool has been introduced into the guiding catheter;

FIGS. 11A, 11B and 11C are cross-sectional views of FIG. 11, taken respectively across lines 11A—11A, 11B—11B and 11C—11C thereof;

FIG. 12 is a view similar to FIG. 9 after the positioning catheter has been introduced into the guiding catheter over the tool shaft;

FIG. 12A is a cross-sectional view of FIG. 12, taken across line 12A—12A thereof;

FIG. 13 is a perspective view of another modified embodiment of the invention;

FIG. 13A is a cross-sectional view, partially broken away, of FIG. 13 taken along line 13A—13A thereof;

FIG. 13B is a cross-sectional view similar to FIG. 13A shown in a moved position;

FIG. 14 is a cross-sectional view similar to FIG. 13B showing a modified embodiment of the invention;

FIG. 15 is a modified embodiment of the invention;

FIG. 15A is a cross-sectional view of FIG. 15, taken along line 15A—15A thereof;

FIG. 16 is yet another modified embodiment of the invention;

FIG. 16A is a view of the other side of the embodiment shown in FIG. 16;

FIG. 17 is a perspective view of yet another embodiment of the invention;

FIG. 18 is a perspective, partially broken-away view of a yet one more embodiment of the invention;

FIG. 19 is a schematic illustration of a cardiopulmonary support/bypass system utilized in conjunction with the decalcification apparatus of the invention;

FIG. 20 shows a modified arrangement of the cardiopulmonary support system of FIG. 19;

FIG. 21 shows a modified arrangement of the cardiopulmonary support system of FIG. 19;

FIG. 22 shows a modified arrangement of the cardiopulmonary support system of FIG. 19;

FIG. 23 shows a modified arrangement of the cardiopulmonary support system of FIG. 19;

FIG. 24 is a cross-sectional view of an anchoring balloon of the invention; FIG. 25 is a cross-sectional view of a modified embodiment of the anchoring balloon of the invention;

FIG. 26 is a cross-sectional view of another modified embodiment of an anchoring balloon of the invention;

FIG. 26A is a cross-sectional view of FIG. 26, taken along line 26A—26A thereof;

FIG. 27A is a perspective, broken-away view in partial cross-section showing yet another embodiment of the apparatus of the invention;

FIG. 27B shows the proximal ends of the various catheters utilized in the embodiment of FIG. 27A;

FIG. 28 shows a modified version of the embodiment of FIG. 27A;

FIG. 29 shows the embodiment of FIG. 27A inserted into position prior to inflation of the anchoring balloon;

FIG. 30 shows an alternate embodiment, partially broken away, similar to FIG. 29;

FIG. 31 shows another modified embodiment of the invention;

FIGS. 32A and 32B show yet another modified embodiment of the invention; and

FIGS. 33—35 show alternate deposit removal tools usable with the apparatus of the invention.

BEST MODE FOR CARRYING OUT THE INVENTION

FIG. 1 shows in perspective, partial cross-sectional view an anchoring balloon catheter 24 of the invention secured in the aorta 10, with its distal portion 25 inserted past the leaflets 12 of the aortic valve. In FIG. 2, a portion of the valve leaflets 12 in the foreground has been omitted to reveal better the position and shape of the distal portion 25 of the anchoring balloon catheter 24 and the deposits 15 on the superior surface 13 of the leaflets. In this view, it can be seen that the distal portion 25 of the anchoring balloon is preferably of a larger diameter, having a shoulder 26 that contacts the inferior surface of the valve leaflets 12 to accurately and securely position the anchoring balloon 24, with respect to the valve leaflets 12, providing support to the leaflets to stabilize their positions and to outline the inferior surface of the leaflets 12 in contact with the balloon inflated with radiographic contrast solution. The anchoring balloon catheter 24 also includes a central catheter 21 having preferably at least a pair of lumens, one 22 for passage of the anchoring balloon catheter 24 over a guide wire (not shown) and/or injection or withdrawal of fluids therethrough, and a second 23 for inflation of the balloon 24.

Attachment means is provided to secure a deposit removal tool 40 to the inflatable anchoring balloon catheter 24. The attachment means may comprise a variety of configurations. A preferred embodiment is depicted in FIGS. 1-5. In this embodiment, the attachment means includes means for selectively positioning the deposit removal tool 40 with respect to the anchoring balloon 24 so that the physician can guide the tool 40 carefully to the calcification deposit 15 which is to be removed. Again, the preferred embodiment illustrated in FIGS. 1-5 shows a preferred mechanism for achieving this selective control.

In this preferred embodiment, a circumferential band 60 having first and second ends 62 and 64, respectively, is attached to the anchoring balloon 24. The circumferential band 60 also includes an intermediate portion 66, which is attached to a guiding catheter 42. The deposit removal tool 40 in turn is disposed within the guiding catheter 42.

As mentioned above, preferably means is provided for selectively moving the guiding catheter 42 about the periphery of the anchoring balloon 24. In this preferred embodiment, a pair of positioning balloons 70 and 76 are disposed between the circumferential band 60 and the anchoring balloon 24, each located adjacent the ends 62 and 64 of the circumferential band 60. As illustrated in FIGS. 3-5, the guiding catheter 42 can be moved about the periphery of the anchoring balloon 24 by selectively inflating and deflating the positioning balloons 70 and 76.

In FIG. 3, both of the positioning balloons 70 and 76 are partially inflated, and the guiding catheter 42 is in a generally central position. In FIG. 4, one of the positioning balloons 70 has been fully inflated and the other positioning balloon 76 deflated, causing the guiding catheter 42 to have moved to its most clockwise location. In FIG. 5, the first positioning balloon 70 is fully deflated, and the second positioning balloon 76 is fully inflated, causing the circumferential band 60 to pull the guiding catheter 42 to its most counterclockwise position. Thus, by selectively inflating and deflating the positioning balloons 70 and 76, the guiding catheter 42 can be moved through a range of positions about the anchoring balloon 24. The size of the positioning balloons and the diameter of the anchoring balloon will dictate what total range of motion is possible. Preferably, the range of motion should be at least about 120°, allowing the deposit removal tool 40 to fully service one of the three leaflets 12 of the aortic valve without repositioning the anchoring balloon 24. To remove deposits from the other leaflets 12, the anchoring balloon 24 can be partially deflated and then rotated to a new position corresponding to one of the other leaflets 12.

FIGS. 3-8 depict a secondary positioning means that allows some control over the radial position of the deposit removal tool 40. In this embodiment, a positioning catheter 46 is disposed within the guiding catheter 42. The positioning catheter 46 includes an off-center lumen 49 in which the shaft 41 of the deposit removal tool 40 is carded. By rotating the positioning catheter 46 with respect to the guiding catheter 42, the deposit removal tool 40 can be adjusted radially inwardly and outwardly with respect to the anchoring balloon 24. Some limited control over the circumferential position of the tool 40 is also provided.

FIGS. 6-8 illustrate a particularly preferred embodiment in which the positioning catheter 46 includes in-

dexing slots 47 at its distal end. The guiding catheter 42 in turn carries a tab 43 extending radially inwardly (the tab 43 may, e.g., extend radially inwardly from a metal ring 45 carded by the guiding catheter 42). As the positioning catheter 46 is advanced through the guiding catheter 42 to its most distal position, the tab 43 of guiding catheter 42 will engage a corresponding slot 47 in the positioning catheter 46. This prevents rotational movement of the positioning catheter 46 with respect to the guiding catheter as the tool is being utilized. Where it is desired to change the rotational position of the positioning catheter 46, it can be withdrawn slightly, rotated, and then again advanced to engage the tab 43 in the desired slot 47 corresponding to the desired position.

FIGS. 9-12 illustrate another modification of the invention which includes a collapsible sheath 44, and illustrate its use in the process of introducing the device of the invention into the patient. In FIG. 9, the aorta 10 is shown schematically dividing into the left and right iliac arteries 11. The anchoring balloon catheter 24 with its catheter 21 has been inserted into the iliac artery 11, and advanced through the aorta to the aortic valve, where the anchoring balloon 24 is inflated. In this embodiment, a flaccid sheath 44 is connected directly to the circumferential band 60. This flaccid sheath allows final assembly of the entire unit inside the body—i.e., the anchoring balloon with the flaccid sheath 44, the circumferential band 60 and the positioning balloons 70 and 76 (all deflated and furled about the catheter 21 of the anchoring balloon 24) can first be inserted into the aorta 10 via the iliac artery 11. The guiding catheter, positioning catheter and deposit removal tool can then be inserted, after the anchoring balloon catheter is in position. The flaccid nature of this sheath 44 therefore allows the deflated anchoring balloon 24 with attachment means to be furled into a relatively small diameter unit for insertion through the narrower iliac artery 11 into the wider aorta 10. Once the anchoring balloon 24 has entered the aorta 10 (and, preferably, reached its position in the aortic valve), the anchoring balloon 24 can be inflated and the rest of the unit assembled by inserting the guiding catheter 42 through the sheath 44 to its position adjacent the anchoring balloon 24, followed by the deposit removal tool and the positioning catheter. To ease insertion of the guiding catheter into the sheath 44, the sheath can be of a larger diameter proximally, narrowing at its most distal portion to a diameter that closely receives the guiding catheter therein.

In FIG. 9, the guiding catheter 42 has been advanced only slightly into the sheath 44. In FIG. 10, the guiding catheter 42 is fully advanced, and the deposit removal tool 40 is about to be introduced. Note that FIGS. 10A and 10B illustrate the cross-sectional configuration of the device, and show catheter 19 with four lumens—one each 71 and 77 for inflating and deflating the positioning balloons 70 and 76, one 23 for inflating the anchoring balloon itself, and one 22 for passing through a guide wire or injecting or withdrawing fluids such as contrast or blood. The catheter 19 is formed from catheter 21 of the anchoring balloon catheter 24 and catheters 72 and 78 of the positioning balloons 70 and 76, respectively.

In FIG. 11 the deposit removal tool 40 has been fully advanced through the guiding catheter 42 and the positioning catheter 46 is about to be advanced over the shaft 41 of the deposit removal tool 40. FIG. 11A depicts the tool's shaft 41 closely received in the off-center

lumen 49 of the positioning catheter 46. FIG. 12 shows the positioning catheter 46 fully advanced through the guiding catheter 42. A "Y" connector 52 may be provided on the proximal end of the positioning catheter 46 to allow fluid to be injected or withdrawn through the main lumen 50 of the positioning catheter 46, while the elongated shaft 41 of the tool 40 exits through a sealing fitting 51. In most applications, the main lumen 50 will be utilized to withdraw fluid from the area immediately adjacent the deposit removal tool, thereby removing any particles or debris cut away by the tool. This lumen 50 may also be used, however, for injecting fluids, such as contrast solutions used in radiographic imaging.

FIGS. 13-14 depict an alternate embodiment for providing attachment means to secure the tool 40 with respect to the anchoring balloon 24 and for permitting selected positioning of the deposit removal tool 40 with respect to the anchoring balloon 24. In this embodiment, a set of circumferential straps is provided. In the embodiment illustrated, a set of upper and lower circumferential straps 85 is attached with a first end 86 secured to the anchoring balloon 24 and a second end 87 attached to the guiding catheter 42. A middle strap 90 similarly has a first end 91 attached to the anchoring balloon 24 and a second end 92 attached to the guiding catheter 42. The middle strap 90 is wound about the anchoring balloon 24 in a direction opposite that of the upper and lower straps 85. The guiding catheter 42 may then be rotated to move it circumferentially about the anchoring balloon 24. Referring to FIGS. 13A-13B, as the guiding catheter is rotated clockwise, the middle strap 90 will wind up on the guiding catheter 42, while the upper and lower straps 85 will unwind from the guiding catheter 42; as this occurs, the guiding catheter 42 will move clockwise about the anchoring balloon 24 from the position illustrated in FIG. 13A to the position illustrated in FIG. 13B. FIG. 14 shows a slightly modified arrangement of this embodiment where the straps 85 and 90 are somewhat longer, permitting movement of the guiding catheter 42 substantially entirely around the anchoring balloon 24.

FIGS. 15 and 15A show another simplified embodiment of the invention. In this embodiment guiding catheter 42 is attached directly to the wall of the anchoring balloon 24. Positioning of the tool is accomplished merely by rotating the anchoring balloon 24 itself with respect to the aortic valve, and by rotating the positioning catheter 46 within the guiding catheter 42.

FIGS. 16-16A show yet another embodiment for controllably positioning the guiding catheter with respect to the anchoring balloon (FIG. 16A showing the back side of FIG. 16). In this embodiment a pair of cords 57 can be manipulated to move the guiding catheter 42 about the periphery of the anchoring balloon 24. Each cord 57 is attached at its distal end 57a to a pulley strip 59 that in turn is attached to the anchoring balloon (FIG. 16A). The cord is then threaded through a series of pulleys on a pair of pulley rings 58 carried by the guiding catheter 42 and pulleys on the fixed pulley strip 59. By pulling on one of the cords 57 while releasing the other the guiding catheter will be pulled around the anchoring balloon in one direction; by pulling on the other cord, the guiding catheter will be pulled around in the other direction.

In practice, the decalcification procedure of the invention proceeds as follows. Access to the aorta 10 is obtained, typically through percutaneous or cut-down entry into the femoral artery with a guide wire. The

guide wire is advanced through the femoral and iliac arteries and the aorta to the aortic valve and then across the aortic valve into the left ventricle (L.V.). A deflated anchoring balloon catheter 24 is then advanced over the guide wire to a position across the aortic valve with the distal tip of the balloon in the left ventricle (L.V.). The anchoring balloon 24 is then inflated and slightly retracted to engage the shoulder 26 of the anchoring balloon 24 against the inferior surface of the calcified valve leaflets 12. (Depending on the situation and the type of anchoring balloon catheter utilized, cardiopulmonary support/bypass may be necessary once the balloon is inflated, and this can be accomplished as described below.)

When utilizing the embodiment having the collapsible guiding catheter sheath 44 attached to the anchoring balloon 24, the guiding catheter 42 may then be advanced through the sheath 44 to proper position adjacent the anchoring balloon 24. The deposit removal tool 40, together with the positioning catheter 46, may then be advanced through the guiding catheter 42 to their proper positions. One or both of the positioning balloons 70, 76, may then be inflated to circumferentially locate the guiding catheter 42 and, hence, the deposit removal tool 40 as desired. The positioning catheter may also be rotated to further position the removal tool 40. The tool 40 in turn may also be slightly advanced or withdrawn as necessary. Operation of the removal tool 40 can then be commenced, with blood and dislodged calcification deposits being sucked up through the main lumen 50 of the positioning catheter 46. When deposits from a particular leaflet 12 have been removed, the anchoring balloon 24 can be deflated partially and rotated to position the removal tool 40 adjacent one of the other leaflets 12. When the calcification deposits have been removed, the entire device may be removed essentially by reversing the process of inserting the device.

During the procedure, conventional radiographic imaging techniques may be utilized to allow the physician to view the relative locations of the anchoring balloon 24, deposit removal tool 40, and the calcified deposits which are to be removed from the aortic valve leaflets. Preferably, the components of the anchoring balloon and removal tool and associated catheters are either radio-opaque or marked with radio-opaque markers so that they will be visible by conventional radiographic imaging techniques. Visualization of the anchoring balloon and positioning balloons and the inferior surface of the leaflets in contact with the anchoring balloon 24 is further facilitated by using radiographic contrast solution for inflation of the balloons 24, 70 and 76. Contrast may also be injected either through the lumen 22 of the anchoring balloon 24, or through the main lumen 50 of the positioning catheter 46.

In addition, known ultrasound imaging techniques may also be utilized. N. Bom and J. Roelandt have edited a reference book entitled "Intravascular Ultrasound," (Kluwer Academic Publishers 1989), containing a variety of articles detailing techniques, developments, and clinical perspectives on intravascular ultrasound procedures. FIG. 17 illustrates one possible embodiment utilizing a phased array ultrasound transducer 29 (containing many small acoustic elements 128) mounted on the catheter 21 of the anchoring balloon 24. This transducer 29 will generate a cross-sectional view of the aortic valve and the location of the calcified deposits to be removed. The details of such ultrasound techniques for intravascular imaging are well-known, as

described in the above-mentioned text. Ultrasound preferably is used in conjunction with and not to the exclusion of conventional radiographic imaging.

FIG. 18 shows another embodiment of the invention where an ultrasound catheter 132 is positioned inside one of the lumens of the catheter 21 of the anchoring balloon 24, preferably the lumen 22. The ultrasound catheter 132 shown in FIG. 18 operates on a principle different from the one shown in FIG. 17. Instead of a phased array transducer, the ultrasound catheter 132 includes an echo transducer 133 and a mirror 31 rotated by a flexible shaft 30. This embodiment is advantageous in that it allows the ultrasound catheter 132 to be advanced or retracted in the lumen 22 of the anchoring balloon 24 to provide a cross-sectional image at the desired more distal or more proximal position. As these types of ultrasound catheters and procedures are described in greater detail in the Bom reference identified above, further description is not necessary-here.

During performance of the decalcification procedure, it is desirable to provide cardiopulmonary support/bypass for the patient, as an anchoring balloon 24 of the type depicted in FIG. 1 substantially occludes the aortic valve. FIGS. 19-23 depict several variations for providing such support.

FIG. 19 depicts in schematic form a first variation. Blood is ejected/withdrawn from the left ventricle through the central lumen 22 of the anchoring balloon catheter 24 and delivered to a first pump 106. That pump 106 in turn delivers the blood through a filter 107 to a heat exchanger 108 and then through percutaneous catheter 111 back to the iliac artery 11 and the aorta 10. Blood and calcification deposit debris loosened by the removal tool 40 are aspirated into the main lumen 50 of the positioning catheter containing the tool shaft by a second pump 110. Debris is filtered out by a second filter 109, after which the blood is sent through the heat exchanger 108 and the return catheter 111 back to the aorta 10.

To assure adequate extracorporeal circulation an additional blood withdrawal catheter 113 is percutaneously introduced into the iliac vein 120. Blood withdrawn through this catheter 113 should be oxygenated before being returned to the body. This may be accomplished by a conventional oxygenator 105 which in turn passes the blood through pump 106 to filter 107, and heat exchanger 108, whereupon the blood may be returned to the aorta 10 through the return catheter 111.

In order to maintain blood flow through the heart sufficient to significantly reduce the risk of cardiac asystole, particularly in light of the relatively small size of the central lumen 22 of the anchoring balloon catheter 24, a supplemental catheter 112 may be advanced percutaneously through the vena cava 100 to the left ventricle (L.V.) by way of the right atrium (R.A.) and the left atrium (L.A.), as shown in FIG. 20. To achieve this positioning of the catheter 112, the catheter must pass through the thin septum between the right atrium (R.A.) and left atrium (L.A.), such as is commonly done in mitral balloon valvuloplasty (see, e.g., T. Bashore, "Invasive Cardiology Principles and Techniques" (B.C. Decker Inc.) at pp. 147ff). This catheter 112 may be of substantial diameter in comparison to the central lumen 22 of the anchoring balloon catheter 24. Blood ejected/withdrawn through this catheter 112 passes from pump 106 through filter 107 to heat exchanger 108 and then through the return catheter 111 back to the aorta 10. Catheters 112 and 113 may be arranged in a double

lumen catheter, which may be a side by side double lumen, a coaxial double lumen, or even a single lumen catheter that has holes in a wall thereof in an intermediate portion, defining the distal "end" of the vein access catheter 113.

The foregoing blood paths through the lumen 22 of the anchoring catheter 24 and through catheter 112 usually will allow sufficient cardiac output to prevent cardiac asystole.

FIG. 21 depicts an alternate arrangement for external blood flow. In this configuration, the blood withdrawn from the left ventricle of the heart (through the larger catheter 112 and through the central lumen 22 of the anchoring balloon catheter 24) is passed directly to the oxygenator 105 before being returned (via pump 106, filter 107 and heat exchanger 108) to the aorta 10 through return catheter 111. In yet another configuration shown in FIG. 22, all of the blood withdrawn from the heart is first passed through pump 110 and the second filter 109 before being sent to the oxygenator 105.

In yet a further embodiment shown in FIG. 23, an additional pump 114 is provided upstream from the oxygenator but separate from the second pump 110, thereby permitting separate control of the blood withdrawn by the main lumen 50 of the catheter containing the deposit removal tool. Other equivalent arrangements may also be utilized. The arrangements depicted in FIGS. 19-23 demonstrate, however, that cardiac function and coronary circulation can be maintained even while the decalcification procedure is being performed. Rapid cardiac pacing at about 180-200 beats per minute also may be employed to lower cardiac output, particularly when the trans-septal approach to the left ventricle (L.V.) is not used.

FIGS. 24-26A depict possible configurations for the anchoring balloon of the invention. FIG. 24 shows in cross section the anchoring balloon depicted in FIG. 1 and many of the other figures. The balloon includes a distal portion 25 that is of a larger diameter than the rest of the balloon, thereby providing a shoulder 26 for engaging and supporting the inferior surface of the valve leaflets 12—the balloon is inserted past the leaflets 12 and then inflated as it is withdrawn to allow the shoulder 26 to seat against the inferior surface of the valve leaflets 12.

In FIG. 25 the anchoring balloon 24 includes an enhanced shoulder 26 formed by constructing a distal chamber 27 which is in fluid communication with the main chamber 28. The enhanced shoulder 26 provides an even more secure engagement against the inferior surface of the valve leaflets 12. FIG. 26 shows a modified version of the balloon of FIG. 25 wherein the main chamber is merged with the distal chamber, but the enhanced shoulder 26 is preserved. FIG. 26A shows a cross-section of the anchoring balloon catheter 24 with the catheter 21 having two lumens, the lumen 22 through which a guide wire may be advanced or withdrawn and through which fluid may be withdrawn or injected, and the lumen 23 which communicates with the interior of the balloon to inflate and deflate it. Any of the embodiments of FIGS. 24-26A can be modified so that the shoulder portion is manufactured from a thin layer of stretchable material (such as silicone) and the remaining portion of the balloon from a substantially non-stretchable material (or a stretchable material that is reinforced so that it will not stretch beyond a certain point). With this construction, the balloon can be controllably inflated so that the thin, stretchable shoulder

portion 26, which engages and supports the leaflets 12 of the aortic valve, will conform very closely to the shape of the leaflet, giving close, uniform support to the leaflet.

FIGS. 27A-30 depict an alternate embodiment of the invention that may partially or entirely eliminate the need for the cardiopulmonary support/bypass system depicted in FIGS. 19-23. In this embodiment, the anchoring balloon 24' consists of an inflatable tube 32 coiled into a helical configuration and held in this helical configuration by an inner sheath or skin 33, defining a large bore lumen 34. The helical anchoring balloon 24' allows its large bore lumen 34 to present a substantially open passageway distally and proximally, allowing blood to continue flowing through the balloon even when it is inflated and holding the valve leaflets 12 in position for the decalcification procedure. If desired, a rotating screw-type pump 35 may be secured in the proximal portion of the balloon to maintain circulation through the aorta 10 while the procedure is being performed. Such screw-type pumps are well known, such as the HEMOPUMP® brand pump available through Johnson & Johnson. (FIG. 28 shows that multiple screw pumps may be used in parallel to increase the volume of blood pumped. FIG. 28 also shows that one of the screw pumps—e.g., the proximal one—may be used to pump blood from the main lumen 50 of the positioning catheter through the filter 124 at the proximal end of such screw pump.)

A catheter 39 (FIG. 27A) is disposed in the central portion of the distal end of the helical anchoring balloon 24'. The catheter 39 is carrying the phased array ultrasound transducers 29, described previously. The ultrasound catheter 39 desirably exits the large bore lumen 34 through the skin 33 intermediate of the position of the screw pump 35 and the distal end of the helical anchoring balloon 24'. To allow assembly of the catheter into the helical anchoring balloon 24' after insertion of the balloon into the patient, a flaccid sheath 139 may be attached to the skin 33 at the point of entry of the catheter into the large bore lumen 34. Thus, the deflated, furled balloon may be first inserted; once in position, it can be inflated, and the catheter 39 can then be inserted through the flaccid sheath 139 to its position as shown in FIG. 27A. A guide wire 136 may also be advanced via the flaccid sheath 139 or via the lumen of the catheter 39 as necessary.

FIG. 27B shows the proximal end of the various catheters and lumens attached to the configuration in FIG. 27A, including the catheter 39 (containing leads for the ultrasound transducer 29), the drive shaft 38 for the screw pump 35, a syringe (or similar inflation device) 80 connected to the proximal end of tube 32 for inflating the anchoring balloon, inflation devices 73 and 79, respectively, for the first and second positioning balloons, a blood pump 110 for withdrawing blood through the main lumen 50 of the positioning catheter 46, a blood filter 109 and a return catheter 111 to return filtered blood back to an artery (usually the aorta).

FIG. 29 depicts the configuration of the device shown in FIG. 27A and B immediately after it has been advanced over the guide wire 136, but prior to being inflated/unfurled. In FIG. 29, the helical anchoring balloon 24' is in a deflated, furled configuration (the view shows in partial cross-section the layers of helical tubes 32 furled upon one another). A release string 55 may be provided to maintain the distal end of the device in a furled configuration; when the string is withdrawn,

it releases the balloon to be inflated. FIG. 30 shows a modified embodiment where a release strap 56 is adhesively attached to the distal portion of the furled helical anchoring balloon 24' (rather than the string 55) to keep it in furled configuration. When the strap is withdrawn, it similarly releases the balloon to be inflated.

FIG. 31 depicts yet another embodiment of the invention that facilitates blood flow through the helical anchoring balloon catheter 24' while the procedure is being performed. A series of check valve flaps 81, covering orifices 82 in the skin 33 of the anchoring balloon, is provided proximally of the aortic valve to permit blood to flow outwardly through such orifices 82 into the aorta during systole. During diastole, the valve flaps 81 close, similarly to the function of the aortic valve itself, to prevent reflux of the blood into the left ventricle. (Check valves of this type would also be usable with the anchoring balloon catheter 24 of FIG. 1.) FIGS. 32A and 32B show alternate embodiments wherein the helical anchoring balloon 24' in its proximal portion includes a preferably trileaflet valve 83 similar in shape and function to the natural aortic valve.

Although most of the figures depict the deposit removal tool as being a conventional rotatable burr or similar cutting or abrasive device, any other suitable tool may also be employed. FIGS. 33-35 depict three other possibilities. In FIG. 33, a laser 140 (preferably located external to the patient) is connected to a fiberoptic strand 141 which has a distal end positionable adjacent the calcified deposits to be removed. In FIG. 34, an ultrasonic vibration generator 144 (e.g., of the type that generates vibrations in the range of 20,000 Hz) is connected to a wire 145 having a distal tip positionable adjacent the calcified deposits, the wire 145 being capable conveying ultrasonic vibrations. In FIG. 35 a high voltage source 147 is connected to a pair of electrically conductive wires 148 having distal tips positionable adjacent the calcified deposits for generating an arc to destroy the deposits. Tools of other suitable configurations may similarly be utilized.

The components of the anchoring balloon catheter 24 of the invention may be manufactured from any suitable materials, including conventional plastics, silicones, etc. that are biocompatible and possess the desired flexibility/rigidity properties, as the case may be, to perform the desired functions. Such materials are well known, being utilized commonly in current balloon catheters and other intravascular devices. The helical balloon of the invention may be manufactured by any suitable techniques, such as by winding tube 32 into a coiled configuration (as by winding it upon a mandrel) and then securing the turns by either applying an outer skin (or an inner skin, if desired). Such a skin may be formed by applying a thin layer of adhesive, by securing a thin layer of flexible plastic, or by any other suitable means.

While a preferred embodiment of the present invention has been described, it should be understood that various changes, adaptations and modifications may be made therein without departing from the spirit of the invention and the scope of the appended claims.

What is claimed is:

1. A method of removing deposits from an aortic heart valve having a superior surface, comprising;
 - advancing through the aorta an anchoring balloon and a deposit removal tool movably connected with respect to an exterior surface of the anchoring balloon;

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positioning the anchoring balloon across the aortic valve and positioning the deposit removal tool near the superior surface of the aortic valve; inflating the anchoring balloon sufficiently to fixate it with respect to the aorta and aortic valve without completely collapsing the aortic valve; and operating the deposit removal tool to remove the deposits.

2. The method of claim 1 wherein the anchoring balloon catheter includes a proximally extending lumen, the method including the steps of withdrawing blood through the lumen of the anchoring balloon catheter, optionally utilizing a pump, optionally oxygenating such blood, and then returning such blood to an artery.

3. The method of claim 2 wherein the anchoring balloon lumen includes an opening adjacent to the deposit removal tool, the blood withdrawing step comprising withdrawing blood adjacent the deposit removal tool.

4. The method of claim 3 further comprising filtering such blood and returning it to an artery.

5. The method of claim 1 further comprising the step of imaging the area adjacent the anchoring balloon.

6. The method of claim 5 wherein the imaging step comprises radiographic imaging.

7. The method of claim 5 wherein the imaging step includes imaging with ultrasound utilizing an ultrasound transducer carried by the anchoring balloon.

8. The method of claim 1 wherein the step of advancing the deposit removal tool through the aorta is performed after the anchoring balloon has been inflated.

9. The method of claim 8 wherein the step of advancing the deposit removal tool comprises advancing the tool through a catheter that has its distal end secured with respect to exterior surface of the anchoring balloon.

10. The method of claim 1 wherein the step of advancing the anchoring balloon includes the step of si-

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multaneously advancing the deposit removal tool and the anchoring balloon through the aorta.

11. The method of claim 1 further comprising the steps of advancing a blood removal catheter through the vena cava to the right atrium and through the atrial septum to the left atrium and into the left ventricle, and then removing blood from the left ventricle through such catheter and returning such blood to an artery while the anchoring balloon is positioned across the aortic valve.

12. The method of claim 1 further comprising the steps of providing cardiopulmonary bypass support by inserting a vein access catheter into an artery, withdrawing blood through the vein access catheter, oxygenating the blood and returning it to the artery through an artery access catheter.

13. A method of removing deposits from the aortic valve of a heart, comprising;

advancing a deflated, furled anchoring balloon through the aorta and positioning it across the aortic valve, the anchoring balloon including a collapsible guiding catheter sheath;

inflating the anchoring balloon sufficiently to fixate it with respect to the aorta and aortic valve without completely collapsing the aortic valve;

advancing a guiding catheter and a deposit removal tool through the guiding catheter sheath after the anchoring balloon has been inflated and positioning the deposit removal tool near the superior surface of the aortic valve; and

operating the deposit removal tool to remove the deposits.

14. The method of claim 13 further comprising withdrawing blood from the left ventricle of the heart through a catheter, and returning such blood to the aorta.

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